



**ARIZONA DEPARTMENT OF  
HEALTH SERVICES**  
1740 W. Adams Street, Room 303  
Phoenix, Arizona 85007  
(602) 542-1040  
(602) 542-1741 Fax

**SOLICITATION NUMBER: HP861156**

**March 31, 2008, 3:00 P.M., MST.**

**Arizona Department of Health Services  
Office of Procurement  
1740 West Adams Street, Room 303  
Phoenix, Arizona 85007**

## NEWBORN SCREENING LABORATORY SERVICES

<b>PRE-OFFER CONFERENCE:</b>	<u>March 12, 2008</u>	<u>10:00am</u>	<u>1740 W. Adams Street, Room 411A</u>
	<b>Date</b>	<b>Time</b>	<b>Location</b>

In accordance with A.R.S. §41-2534, competitive sealed proposals for the services specified will be received by the Arizona Department of Health Services at the above specified location, until the time and date cited. Offers received by the correct time and date will be opened and the name of each Offeror will be publicly read. To obtain a copy or review the solicitation, log onto [www.azdhs.gov](http://www.azdhs.gov) and click on the Quick Links Procurement site. If obtaining a copy via the internet, please check periodically for any updates to the above solicitation. Amendments may be issued to this solicitation at any time. It is the responsibility of the supplier/Offeror to routinely check the ADHS website for solicitation amendments.

Offers must be in the actual possession of the Arizona Department of Health Services on or prior to the time and date, and at the location indicated above. **Late offers will not be considered.**

Offers must be submitted in a sealed envelope or package with the Solicitation number and the Offeror's name and address clearly indicated on the envelope or package. All offers must be completed in ink or typewritten. Additional instructions for preparing an offer are included in this solicitation.

With 72 hours prior notice, persons with disabilities may request special accommodations such as interpreters, alternative formats, or assistance with physical accessibility. Such requests are to be addressed to the Solicitation Contact Person named below.

**OFFERORS ARE STRONGLY ENCOURAGED TO CAREFULLY READ THE ENTIRE SOLICITATION**

**Solicitation Contact Person: Jamie Alton**  
**(602) 542-1043 / [Altonj@azdhs.gov](mailto:Altonj@azdhs.gov)**

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## UNIFORM INSTRUCTIONS TO OFFERORS

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**A. Definition of Terms.** As used in these Instructions, the terms listed below are defined as follows:

1. *"Attachment"* means any item the Solicitation requires an Offeror to submit as part of the Offer.
2. *"Contract"* means the combination of the Solicitation, including the Uniform and Special Instructions to Offerors, the Uniform and Special Terms and Conditions, and the Specifications and Statement of Scope of Work; the Offer and any Best and Final Offers; and any Solicitation Amendments or Contract Amendments.
3. *"Contract Amendment"* means a written document signed by the Procurement Officer that is issued for the purpose of making changes in the Contract.
4. *"Contractor"* means any person who has a Contract with the State.
5. *"Days"* means calendar days unless otherwise specified.
6. *"Exhibit"* means any item labeled as an Exhibit in the Solicitation or placed in the Exhibits section of the Solicitation.
7. *"Offer"* means bid, proposal or quotation.
8. *"Offeror"* means a vendor who responds to a Solicitation.
9. *"Procurement Officer"* means the person, or his or her designee, duly authorized by the State to enter into and administer Contracts and make written determinations with respect to the Contract.
10. *"Solicitation"* means an Invitation for Bids ("IFB"), a Request for Proposals ("RFP"), or a Request for Quotations ("RFQ").
11. *"Solicitation Amendment"* means a written document that is signed by the Procurement Officer and issued for the purpose of making changes to the Solicitation.
12. *"Subcontract"* means any Contract, express or implied, between the Contractor and another party or between a subcontractor and another party delegating or assigning, in whole or in part, the making or furnishing of any material or any service required for the performance of the Contract.
13. *"State"* means the State of Arizona and Department or Agency of the State that executes the Contract.

**B. Inquiries**

1. **Duty to Examine.** It is the responsibility of each Offeror to examine the entire Solicitation, seek clarification in writing (inquiries), and examine its' Offer for accuracy before submitting the Offer. Lack of care in preparing an Offer shall not be grounds for modifying or withdrawing the Offer after the Offer due date and time, nor shall it give rise to any Contract claim.
2. **Solicitation Contact Person.** Any inquiry related to a Solicitation, including any requests for or inquiries regarding standards referenced in the Solicitation shall be directed solely to the Solicitation contact person. The Offeror shall not contact or direct inquiries concerning this Solicitation to any other State employee unless the Solicitation specifically identifies a person other than the Solicitation contact person as a contact.
3. **Submission of Inquiries.** The Procurement Officer or the person identified in the Solicitation as the contact for inquiries except at the Pre-Offer Conference, require that an inquiry be submitted in writing. Any inquiry related to a Solicitation shall refer to the appropriate Solicitation number, page and

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paragraph. Do not place the Solicitation number on the outside of the envelope containing that inquiry, since it may then be identified as an Offer and not be opened until after the Offer due date and time. The State shall consider the relevancy of the inquiry but is not required to respond in writing.

4. **Timeliness.** Any inquiry or exception to the solicitation shall be submitted as soon as possible and should be submitted at least seven days before the Offer due date and time for review and determination by the State. Failure to do so may result in the inquiry not being considered for a Solicitation Amendment.
5. **No Right to Rely on Verbal Responses.** An offeror shall not rely on verbal responses to inquiries. A verbal reply to an inquiry does not constitute a modification of the solicitation.
6. **Solicitation Amendments.** The Solicitation shall only be modified by a Solicitation Amendment.
7. **Pre-Offer Conference.** If a pre-Offer conference has been scheduled under this Solicitation, the date, time and location shall appear on the Solicitation cover sheet or elsewhere in the Solicitation. Offerors should raise any questions about the Solicitation or the procurement at that time. An Offeror may not rely on any verbal responses to questions at the conference. Material issues raised at the conference that result in changes to the Solicitation shall be answered solely through a written Solicitation Amendment.
8. **Persons With Disabilities.** Persons with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting the Solicitation contact person. Requests shall be made as early as possible to allow time to arrange the accommodation.

#### **C. Offer Preparation**

1. **Forms: No Facsimile, Telegraphic or Electronic Mail Offers.** An Offer shall be submitted either on the forms provided in this Solicitation or their substantial equivalent. Any substitute document for the forms provided in this Solicitation must be legible and contain the same information requested on the forms, unless the solicitation indicates otherwise. A facsimile, telegraphic, mailgram or electronic mail Offer shall be rejected if submitted in response to requests for proposals or invitations for bids.
2. **Typed or Ink; Corrections.** The Offer shall be typed or in ink. Erasures, interlineations or other modifications in the Offer shall be initialed in ink by the person signing the Offer. Modifications shall not be permitted after Offers have been opened except as otherwise provided under applicable law.
3. **Evidence of Intent to be Bound.** The Offer and Acceptance form within the Solicitation shall be submitted with the Offer and shall include a signature (or acknowledgement for electronic submissions, when authorized) by a person authorized to sign the Offer. The signature shall signify the Offeror's intent to be bound by the Offer and the terms of the Solicitation and that the information provided is true, accurate and complete. Failure to submit verifiable evidence of an intent to be bound, such as an original signature, shall result in rejection of the Offer.
4. **Exceptions to Terms and Conditions.** All exceptions included with the Offer shall be submitted in a clearly identified separate section of the Offer in which the Offeror clearly identifies the specific paragraphs of the Solicitation where the exceptions occur. Any exceptions not included in such a section shall be without force and effect in any resulting Contract unless such exception is specifically accepted by the Procurement Officer in a written statement. The Offeror's preprinted or standard terms will not be considered by the State as a part of any resulting Contract.
  - i. **Invitation for Bids.** An Offer that takes exception to a material requirement of any part of the Solicitation, including terms and conditions, shall be rejected.

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- ii. Request for Proposals. All exceptions that are contained in the Offer may negatively affect the State's proposal evaluation based on the evaluation criteria stated in the Solicitation or result in rejection of the Offer. An offer that takes exception to any material requirement of the solicitation may be rejected.
- 5. Subcontracts. Offeror shall clearly list any proposed subcontractors and the subcontractor's proposed responsibilities in the Offer.
- 6. Cost of Offer Preparation. The State will not reimburse any Offeror the cost of responding to a Solicitation.
- 7. Solicitation Amendments. Each Solicitation Amendment shall be signed with an original signature by the person signing the Offer, and shall be submitted no later than the Offer due date and time. Failure to return a signed copy of a Solicitation Amendment may result in rejection of the Offer.
- 8. Federal Excise Tax. The State of Arizona is exempt from certain Federal Excise Tax on manufactured goods. Exemption Certificates will be provided by the State.
- 9. Provision of Tax Identification Numbers. Offerors are required to provide their Arizona Transaction Privilege Tax Number and/or Federal Tax Identification number in the space provided on the Offer and Acceptance Form.
- 9.1 Employee Identification. Offeror agrees to provide an employee identification number or social security number to the Department for the purposes of reporting to appropriate taxing authorities, monies paid by the Department under this contract. If the federal identifier of the offeror is a social security number, this number is being requested solely for tax reporting purposes and will be shared only with appropriate state and federal officials.  
This submission is mandatory under 26 U.S.C. § 6041A.
- 10. Identification of Taxes in Offer. The State of Arizona is subject to all applicable state and local transaction privilege taxes. All applicable taxes shall be included in the pricing offered in the solicitation. At all times, payment of taxes and the determination of applicable taxes are the sole responsibility of the contractor.
- 11. Disclosure. If the firm, business or person submitting this Offer has been debarred, suspended or otherwise lawfully precluded from participating in any public procurement activity, including being disapproved as a subcontractor with any Federal, state or local government, or if any such preclusion from participation from any public procurement activity is currently pending, the Offeror shall fully explain the circumstances relating to the preclusion or proposed preclusion in the Offer. The Offeror shall include a letter with its Offer setting forth the name and address of the governmental unit, the effective date of this suspension or debarment, the duration of the suspension or debarment, and the relevant circumstances relating to the suspension or debarment. If suspension or debarment is currently pending, a detailed description of all relevant circumstances including the details enumerated above shall be provided.
- 12. Solicitation Order of Precedence. In the event of a conflict in the provisions of this Solicitation, the following shall prevail in the order set forth below:
  - 12.1 Special Terms and Conditions;
  - 12.2 Uniform Terms and Conditions;
  - 12.3 Statement or Scope of Work;
  - 12.4 Specifications;
  - 12.5 Attachments;
  - 12.6 Exhibits;
  - 12.7 Special Instructions to Offerors;
  - 12.8 Uniform Instructions to Offerors.

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12.9 Other documents referenced or included in the Solicitation.

13. Delivery. Unless stated otherwise in the Solicitation, all prices shall be F.O.B. Destination and shall include all freight, delivery and unloading at the destination(s).

#### **D. Submission of Offer**

1. Sealed Envelope or Package. Each Offer shall be submitted to the submittal location identified in this Solicitation. Offers should be submitted in a sealed envelope or container. The envelope or container should be clearly identified with name of the Offeror and Solicitation number. The State may open envelopes or containers to identify contents if the envelope or container is not clearly identified.

2. Offer Amendment or Withdrawal. An Offer may not be amended or withdrawn after the Offer due date and time except as otherwise provided under applicable law.

3. Public Record. All Offers submitted and opened are public records and must be retained by the State. Offers shall be open to public inspection after Contract award, except for such Offers deemed to be confidential by the State.  
If an Offeror believes that information in its Offer should remain confidential, it shall indicate as confidential the specific information and submit a statement with its Offer detailing the reasons that the information should not be disclosed. Such reasons shall include the specific harm or prejudice which may arise. The State shall determine whether the identified information is confidential pursuant to the Arizona Procurement Code.

4. Non-collusion, Employment, and Services. By signing the Offer and Acceptance Form or other official contract form, the Offeror certifies that:

- i. The Offeror did not engage in collusion or other anti-competitive practices in connection with the preparation or submission of its Offer; and
- ii. The Offeror does not discriminate against any employee or applicant for employment or person to whom it provides services because of race, color, religion, sex, national origin, or disability, and that it complies with all applicable Federal, state and local laws and executive orders regarding employment.

#### **E. Evaluation**

1. Unit Price Prevails. In the case of discrepancy between the unit price or rate and the extension of that unit price or rate, the unit price or rate shall govern.

2. Prompt Payment Discount. Prompt payment discounts of thirty (30) days or more set forth in an Offer shall be deducted from the offer for the purposes of evaluating that price.

3. Late Offers. An Offer submitted after the exact Offer due date and time shall be rejected.

4. Disqualification. A Offeror (including each of its' principals) who is currently debarred, suspended or otherwise lawfully prohibited from any public procurement activity shall have its offer rejected.

5. Offer Acceptance Period. An Offeror submitting an Offer under this Solicitation shall hold its Offer open for the number of days from the Offer due date that is stated in the Solicitation. If the Solicitation does not specifically state a number of days for Offer acceptance, the number of days shall be one hundred-twenty (120). If a Best and Final Offer is requested pursuant to a Request for Proposals, an Offeror shall hold its Offer open for one hundred-twenty (120) days from the Best and Final Offer due date.

5.6 Waiver and Rejection Rights. Notwithstanding any other provision of the Solicitation, the State reserves the right to:

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- 5.6.1 Waive any minor informality;
- 5.6.2 Reject any and all Offers or portions thereof; or
- 5.6.3 Cancel the Solicitation.

#### **F. Award**

- 1. Number or Types of Awards. The State reserves the right to make multiple awards or to award a Contract by individual line items or alternatives, by group of line items or alternatives, or to make an aggregate award, or regional awards, whichever is most advantageous to the State. If the Procurement Officer determines that an aggregate award to one Offeror is not in the State's best interest, "all or none" Offers shall be rejected.
- 2. Contract Inception. An Offer does not constitute a Contract nor does it confer any rights on the Offeror to the award of a Contract. A Contract is not created until the Offer is accepted in writing by the Procurement Officer's signature on the Offer and Acceptance Form. A notice of award or of the intent to award shall not constitute acceptance of the Offer.
- 3. Effective Date. The effective date of this Contract shall be the date that the Procurement Officer signs the Offer and Acceptance form or other official contract form, unless another date is specifically stated in the Contract.

#### **G. Protests**

A protest shall comply with and be resolved according to Arizona Revised Statutes Title 41, Chapter 23, Article 9 and rules adopted thereunder. Protests shall be in writing and be filed with both the Procurement Officer of the purchasing agency and with the State Procurement Administrator. A protest of a Solicitation shall be received by the Procurement Officer before the Offer due date. A protest of a proposed award or of an award shall be filed within ten (10) days after the protester knows or should have known the basis of the protest. A protest shall include:

- 1.1 The name, address and telephone number of the protester;
- 1.2 The signature of the protester or its representative;
- 1.3 Identification of the purchasing agency and the Solicitation or Contract number;
- 1.4 A detailed statement of the legal and factual grounds of the protest including copies of relevant documents; and
- 1.5 The form of relief requested.

#### **H. Comments Welcome**

The State Procurement Office periodically reviews the Uniform Instructions to Offerors and welcomes any comments you may have. Please submit your comments to: State Procurement Administrator, State Procurement Office, 100 North 15th Avenue, Suite 104, Phoenix, Arizona, 85007

# SPECIAL INSTRUCTIONS TO OFFERORS

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### I. PRE-OFFER CONFERENCE:

Prospective Offerors are invited and encouraged to attend a pre-offer conference. The date, time and location of this conference are indicated on the solicitation cover sheet. The purpose of this conference will be to clarify the contents of this request for proposals in order to prevent any misunderstanding of the Department's position. Any doubt as to the requirements of this request for proposals or any apparent omission or discrepancy should be presented to the Department at this conference or in accordance with the terms and conditions provided herein. The Department will then determine the appropriate action necessary, if any, and may issue a written amendment to the request for proposals. Oral statements or instructions shall not constitute an amendment to this request for proposals.

Those who are planning to attend the pre-offer conference should RSVP to Jamie Alton by email at [altonj@adhs.gov](mailto:altonj@adhs.gov) or by phone at 602-542-1043. It is strongly suggested that Offerors attend the Pre-Offer Conference.

### II. SOLICITATION INQUIRES

Offerors may contact the "Solicitation Contact Person", listed below, with questions regarding the solicitation.

To assist ADHS in preparing for the Pre-Offer Conference, Offerors are encouraged to submit, in writing, any inquiries, clarifications or suggested changes to this Request for Proposal at least seven (7) days before the Pre-Offer Conference. Inquiries regarding the Solicitation will be received and considered beyond 7 days before the Pre-Offer Conference date, but the contents may not be considered in time to respond during the Pre-Offer Conference. Failure to submit, in writing, by the deadline may prevent the ADHS from thoroughly responding during the Pre-Offer Conference. This section does not limit or restrict an Offeror from asking questions or clarifying this Solicitation during the Pre-Offer Conference if written questions, clarifications or suggested changes are not submitted. In addition to a paper copy delivered to the address listed below, an electronic copy, in Microsoft Word format, should be submitted to the following email address: [altonj@azdhs.gov](mailto:altonj@azdhs.gov)

Jamie Alton, Procurement Specialist  
Arizona Department of Health Services  
1740 W. Adams, Room 303  
Phoenix, AZ 85007  
Phone No.: (602) 542 - 1043  
Fax No.: (602) 542 - 1741  
Email Address: [altonj@azdhs.gov](mailto:altonj@azdhs.gov)

### III. PROPOSAL FORMAT

The Instructions to Offerors and terms and conditions should be reviewed and understood before preparing a response. Offerors should carefully review the insurance requirements in the Special Terms and Conditions to ensure they can comply.

The Offeror shall provide one (1) original and seven (7) copies of each proposal. Proposals shall be submitted on the forms and in the format specified in the RFP. The original copy of the proposal should be clearly labeled "ORIGINAL." The material should be in the sequence listed below and related to the RFP. Proposals shall be contained in loose-leaf binders, with section tabs and/or sections separated. Proposals should not be spiral bound or held together with rubber bands or binder clips.

The proposal shall be presented in the following order:

- A. Offer and Acceptance form;
- B. Methodology;



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- C. Price Sheet and assumptions on rate determination;
- D. Offeror's Qualifications Questionnaire and responses to questions;
- E. Experian business report;
- F. Bid Bond;
- G. Proposed Subcontracts and description of selection process, if applicable; and
- H. Signed Solicitation Amendment(s), if applicable.

Please Note, as indicated in the Uniform Instructions, paragraph D.1, Submission of Offer, each Offer shall be submitted to the submittal location identified in this solicitation, in a sealed envelope or container that clearly identifies its contents as an Offer, the Offeror's name and the solicitation number to which it responds.

ADHS will not provide any reimbursement for the cost of developing or presenting proposals in response to this RFP. Failure to include the requested information may have a negative impact on the evaluation of the Offeror's proposal.

#### **2. INSTRUCTIONS FOR PROVIDING THE INFORMATION REQUESTED**

- A. Offer and Acceptance form - The Offeror shall submit two (2) signed originals of the Offer and Acceptance form.
- B. Methodology - The Scope of Work defines the services for which the Contractor shall provide. The first sections of the Scope of Work, I. Objective and II. Background, identify the objective and a general description of the Newborn Screening Program. Section III. Mandatory Requirements are specific requirements the Offeror must have and maintain in providing the required contract services. Section IV. Scope of Services is a general description of the required contract services. Section V. Required Tasks are the specific activities the Contractor shall perform. (Questions regarding Neometrics should be addressed to Neometrics. Neometrics can be contacted at 1-800-645-3616.)

There are specific Sections within the Required Tasks for which the Offeror shall provide additional information as indicated below or a detailed description of the method or activities for accomplishing the Tasks for these Sections. A detailed description shall include the positions/persons responsible for accomplishment of these activities. This shall be labeled "Section VI. Methodology." The Sections of the Required Tasks that need to be addressed are:

Section B, Specimen Collection Kit – Offeror shall identify and provide justification for the type of specimen collection kits they recommend for use. Examples should be provided.

Section G, #10, Performance Requirements – Offeror shall submit their Business Continuity and Disaster Recovery Plan.

Section G, #11, Performance Requirements - Offeror shall submit a methodology and approach for this Section.

Section H, #1, Quality Assurance and Improvement – Offer shall submit their Quality Assurance and Improvement Plan.

Section I, #1, Billing for Newborn Screening Laboratory Tests - Offeror shall submit a methodology and approach for this Section.

Section J, Technical Assistance and Quality Improvement Consultation - Offeror shall submit a methodology and approach for this Section.

Section N, Educational Programs - If Offeror is located outside the Phoenix metropolitan area, Offeror shall describe how it will provide newborn screening educational programs from remote locations.

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Section O, Reference Materials - Offeror shall submit a methodology and approach for this Section.

Section P, Consultation and Program Support Activities – If Offeror is located outside the Phoenix metropolitan area Offeror shall describe how it will provide all of the Consultation and Program Support Activities from remote locations.

Section Q, Transition Plan - Offeror shall submit a detailed transition plan for the change of location and service delivery from the current Newborn Screening contractor, the ADHS State Laboratory, to the Offeror.

The methodology should be limited to addressing the specific task. Attempts to reiterate the Offeror's qualifications/experience will be looked upon negatively. ADHS is looking for specific descriptions of how the offeror intends to provide the service. Vague descriptions or simple confirmations that the offer shall comply will be looked upon negatively.

- C. Price Sheet - The Offeror shall indicate the cost for all Units of Service listed on the Price Sheet. Proposals should be based on testing of approximately 225,000 newborn screening specimens annually, including first, second, repeat and dietary specimen types. The ADHS, Arizona State Laboratory may submit a proposal in response to this RFP. Because it is a subdivision of the State, the State Laboratory will not be required to submit a Bid Bond or Performance Bond as is required by this RFP and the resulting contract. To facilitate a fair price comparison Offerors shall submit pricing that indicates their Rate without the cost of a Bid Bond and Performance Bond and their Rate with the cost Bid Bond and Performance Bond.

The Offeror shall submit in sufficient detail the assumptions for the basis of the proposed Rates for the Units of Service.

ADHS understands that there may be interest in performing additional tests and/or studies on the blood specimens beyond what is required by this Contract. ADHS also understands that there may be monetary value in conducting additional testing and in the information it provides. Nevertheless, Offerors bidding on this proposal shall not include requests or pricing for additional testing and/or studies on the blood specimens. After award, ADHS shall consider such requests in accordance with paragraph 28 of the Special Terms and Conditions.

ADHS shall be under no obligation to approve any requests by the Contractor to perform tests and/or studies on the blood specimens beyond what the awarded Contract requires.

- D. Instructions for completing the Offeror's Qualifications Questionnaire are on the forms.
- E. Offeror shall provide a business credit profile from Experian. No other documentation is acceptable. Offeror can obtain the business credit profile at <http://www.smartbusinessreports.com/> or by calling 1-888-211-0728, option #1. At smartbusinessreports.com search for your company to find what is available. It should be the "ProfilePlusReport" or for companies with limited reporting information there is the "BizVerify Report". Submit the "ProfilePlusReport" if it is available or the "BizVerify Report" if the "ProfilePlusReport" is not available.
- F. The Offeror shall provide a Bid Bond per the requirement of the Special Terms and Conditions.
- G. If the Offeror intends to subcontract for any services, the Offeror shall provide copies of existing contracts or sample contracts it will use. The Offeror shall provide justification for why these subcontractors will be used and a description of the selection process.

#### **IV. REFERENCE DOCUMENTS**

The following documents are available from [http://www.aznewborn.com/newbrnsrn\\_providers.htm](http://www.aznewborn.com/newbrnsrn_providers.htm) or by contacting the ONBS at 602-364-1409:

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1. Newborn Screening Guidelines;
2. Description of Newborn Screening Program;
3. Arizona Revised Statute A.R.S. §36-694 et al, §36-2327 et al, §20-2327 et al, §12-2802 et al and §12-2803 et al; and
4. Arizona Administrative Code R9-13-101 to R9-13-1503 and R9-14-101 to R9-14-709.

### **V. INCLUSIVE OFFERORS:**

If the Offeror uses subcontractors, Offerors are encouraged to make every effort to utilize subcontractors that are small, women owned and/or minority owned business enterprises. Offerors who are committing a portion of their work to such subcontractors shall do so by identifying the type of services and work to be performed including detail concerning Offeror's utilization of small, women-owned and/or minority owned business enterprises. Emphasis should be placed on specific areas that are subcontracted, percentage of contract utilization and how this effort will be administered and managed, including reporting requirements.

### **VI. PROPOSAL OPENING:**

Proposals shall be opened publicly at the time and place designated on the cover page of this document. The name of each Offeror shall be read publicly and recorded. Prices will NOT be read. Proposals will not be subject to public inspection until after contract award.

### **VII. EVALUATION CRITERIA:**

A. In accordance with A.R.S. § 41-2534, competitive sealed proposals, awards shall be made to the responsible Offeror(s) whose proposal(s) is(are) determined in writing to be the most advantageous to the Department based upon the evaluation criteria listed below. The evaluation factors are listed in the relative order of importance.

1. Experience/Expertise/Reliability and Qualifications based on background, history, resources, track record, organization chart, financial statement, and staff resumes;
2. Methodology and Approaches; methods or activities to accomplish the Tasks listed in the Scope of Work; and
3. Cost.

### **VIII. RESPONSIBILITY AND SUSCEPTIBILITY**

1. ADHS will, at a minimum, consider the following in determining Offeror's responsibility as well as the susceptibility of its proposal:

A. Offeror may not be considered responsible or susceptible if it does not satisfy the "Offerors's Qualifications" listed herein.

B. Offeror may not be considered responsible or susceptible if the Offeror has been debarred from the practice of a profession that would otherwise be necessary in the provision of goods and services under any resulting contract.

C. Offerors may not be considered responsible based upon the Offeror's record of performance to

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include factual evidence of the Offeror's failure, which may be frequent and reoccurring, to satisfy the terms of the Offeror's agreements and contractual relationships, with any party. Factual evidence may consist of any documented vendor performance reports, customer complaints and/or negative references. Additional responsibility or susceptibility factors include the Offeror's financial, business, personnel, or other resources, including subcontractors and submission of required bid bond; whether the Offeror is legally qualified to contract with the State; and whether the Offeror promptly supplied all requested information concerning its responsibility.

D. Offeror may not be considered responsible if the Offer was not sufficient to evaluate in accordance with the factors identified in the Solicitation or other necessary offer components. Necessary components include: an indication of the intent to be bound, reasonable or acceptable methodology and approach to perform the Scope of Work, experience, price(s), signed Solicitation amendments, and/or references, and any other data specifically requested in the Solicitation.

E. Offeror may not be considered responsible if the Offer limits the rights of ADHS or the State; the Offer materially changes the RFP, which includes the Scope of Work, terms and conditions, or the Offeror provides misleading or inaccurate information.

#### **IX. DISCUSSION:**

In accordance with A.R.S. §41-2534, after the initial receipt of proposals, the Department reserves the option to conduct discussions with those Offerors who submit proposals determined by the Department to be reasonably susceptible of being selected for award regarding the contract and the relative methods of approach for furnishing the required services.

#### **X. FINAL PROPOSAL REVISION**

In the event discussions are conducted with Offerors, ADHS will issue a written request for Final Proposal Revision. The request for Final Proposal Revision will inform Offerors, that if the Offeror does not submit a Final Proposal Revision, the Offeror's immediate previous written proposed proposal revision will be considered as the Offeror's final proposal revision.

# UNIFORM TERMS AND CONDITIONS

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- 1 Definition of Terms.** As used in this Solicitation and any resulting Contract, the terms listed below are defined as follows:
- 1.1 *“Attachment”* means any item the Solicitation requires the Offeror to submit as part of the Offer.
  - 1.2 *“Contract”* means the combination of the Solicitation, including the Uniform and Special Instructions to Offerors, the Uniform and Special Terms and Conditions, and the Specifications and Statement of Scope of Work; the Offer and any Best and Final Offers; and any Solicitation Amendments or Contract Amendments.
  - 1.3 *“Contract Amendment”* means a written document signed by the Procurement Officer that is issued for the purpose of making changes in the Contract.
  - 1.4 *“Contractor”* means any person who has a Contract with the State.
  - 1.5 *“Days”* means calendar days unless otherwise specified.
  - 1.6 *“Exhibit”* means any item labeled as an Exhibit in the Solicitation or placed in the Exhibits section of the Solicitation.
  - 1.7 *“Gratuity”* means a payment, loan, subscription, advance, deposit of money, services, or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value is received.
  - 1.8 *“Materials”* means all property, including equipment, supplies, printing, insurance and leases of property but does not include land, a permanent interest in land or real property or leasing space.
  - 1.9 *“Procurement Officer”* means the person, or his or her designee, duly authorized by the State to enter into and administer Contracts and make written determinations with respect to the Contract.
  - 1.10 *“Services”* means the furnishing of labor, time or effort by a contractor or subcontractor which does not involve the delivery of a specific end product other than required reports and performance, but does not include employment agreements or collective bargaining agreements.
  - 1.11 *“Subcontract”* means any Contract, express or implied, between the Contractor and another party or between a subcontractor and another party delegating or assigning, in whole or in part, the making or furnishing of any material or any service required for the performance of the Contract.
  - 1.12 *“State”* means the State of Arizona and Department or Agency of the State that executes the Contract.
  - 1.13 *“State Fiscal Year”* means the period beginning with July 1 and ending June 30,
- 2 Contract Interpretation**
- 2.1 **Arizona Law.** The Arizona law applies to this Contract including, where applicable, the Uniform Commercial Code as adopted by the State of Arizona and the Arizona Procurement Code, Arizona Revised Statutes (A.R.S.) Title 41, Chapter 23, and its implementing rules, Arizona Administrative Code (A.A.C.) Title 2, Chapter 7.
  - 2.2 **Implied Contract Terms.** Each provision of law and any terms required by law to be in this Contract are a part of this Contract as if fully stated in it.
  - 2.3 **Contract Order of Precedence.** In the event of a conflict in the provisions of the Contract, as accepted by the State and as they may be amended, the following shall prevail in the order set forth below:
    - 2.3.1 Special Terms and Conditions;
    - 2.3.2 Uniform Terms and Conditions;

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- 2.3.3 Statement or Scope of Work;
- 2.3.4 Specifications;
- 2.3.5 Attachments;
- 2.3.6 Exhibits;
- 2.3.7 Documents referenced or included in the Solicitation.
- 2.4 Relationship of Parties. The Contractor under this Contract is an independent Contractor. Neither party to this Contract shall be deemed to be the employee or agent of the other party to the Contract.
- 2.5 Severability. The provisions of this Contract are severable. Any term or condition deemed illegal or invalid shall not affect any other term or condition of the Contract.
- 2.6 No Parol Evidence . This Contract is intended by the parties as a final and complete expression of their agreement. No course of prior dealings between the parties and no usage of the trade shall supplement or explain any terms used in this document and no other understanding either oral or in writing shall be binding.
- 2.7 No Waiver. Either party's failure to insist on strict performance of any term or condition of the Contract shall not be deemed a waiver of that term or condition even if the party accepting or acquiescing in the nonconforming performance knows of the nature of the performance and fails to object to it.
- 3 Contract administration and operation.**
  - 3.1 Records. Under A.R.S. § 35-214 and § 35-215, the Contractor shall retain and shall contractually require each subcontractor to retain all data and other "records" relating to the acquisition and performance of the Contract for a period of five years after the completion of the Contract. All records shall be subject to inspection and audit by the State at reasonable times. Upon request, the Contractor shall produce a legible copy of any or all such records.
  - 3.2 Non-Discrimination. The Contractor shall comply with State Executive Order No. 99-4 and all other applicable Federal and State laws, rules and regulations, including the Americans with Disabilities Act.
  - 3.3 Audit. Pursuant to ARS § 35-214, at any time during the term of this Contract and five (5) years thereafter, the Contractor's or any subcontractor's books and records shall be subject to audit by the State and, where applicable, the Federal Government, to the extent that the books and records relate to the performance of the Contract or Subcontract.
  - 3.4 Facilities Inspection and Materials Testing. The Contractor agrees to permit access to its facilities, subcontractor facilities and the Contractor's processes or services, at reasonable times for inspection of the facilities or materials covered under this Contract. The State shall also have the right to test, at its own cost, the materials to be supplied under this Contract. Neither inspection of the Contractor's facilities nor materials testing shall constitute final acceptance of the materials or services. If the State determines noncompliance of the materials, the Contractor shall be responsible for the payment of all costs incurred by the State for testing and inspection.
  - 3.5 Notices. Notices to the Contractor required by this Contract shall be made by the State to the person indicated on the Offer and Acceptance form submitted by the Contractor unless otherwise stated in the Contract. Notices to the State required by the Contract shall be made by the Contractor to the Solicitation Contact Person indicated on the Solicitation cover sheet, unless otherwise stated in the Contract. An authorized Procurement Officer and an authorized Contractor representative may change their respective person to whom notice shall be given by written notice to the other and an amendment to the Contract shall not be necessary.

## **UNIFORM TERMS AND CONDITIONS**

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- 3.6 Advertising, Publishing and Promotion of Contract. The Contractor shall not use, advertise or promote information for commercial benefit concerning this Contract without the prior written approval of the Procurement Officer.
- 3.7 Property of the State. Any materials, including reports, computer programs and other deliverables, created under this Contract are the sole property of the State. The Contractor is not entitled to a patent or copyright on those materials and may not transfer the patent or copyright to anyone else. The Contractor shall not use or release these materials without the prior written consent of the State.
- 3.8 Ownership of Intellectual Property. Any and all intellectual property, including but not limited to copyright, invention, trademark, trade name, service mark, and/or trade secrets created or conceived pursuant to or as a result of this contract and any related subcontract ("Intellectual Property"), shall be work made for hire and the State shall be considered the creator of such Intellectual Property. The agency, department, division, board or commission of the State of Arizona requesting the issuance of the contract shall own (for and on behalf of the State) the entire right, title and interest to the Intellectual Property throughout the world. Contractor shall notify the State, within thirty (30) days, of the creation of any Intellectual Property by it or its subcontractor(s). Contractor, on behalf of itself and any subcontractor (s), agrees to execute any and all document(s) necessary to assure ownership of the Intellectual Property vests in the State and shall take no affirmative actions that might have the effect of vesting all or part of the Intellectual Property in any entity other than the State. The Intellectual Property shall not be disclosed by contractor or its subcontractor(s) to any entity not the State without the express written authorization of the agency, department, division, board or commission of the State of Arizona requesting the issuance of this contract.

#### **4 Costs and Payments**

- 4.1 Payments. Payments shall comply with the requirements of A.R.S. Titles 35 and 41, Net 30 days. Upon receipt and acceptance of goods or services, the Contractor shall submit a complete and accurate invoice for payment from the State within thirty (30) days.
- 4.2 Delivery. Unless stated otherwise in the Contract, all prices shall be F.O.B. Destination and shall include all freight delivery and unloading at the destination.
- 4.3 Applicable Taxes.
- 4.3.1 Payment of Taxes. The Contractor shall be responsible for paying all applicable taxes.
- 4.3.2 State and Local Transaction Privilege Taxes. The State of Arizona is subject to all applicable state and local transaction privilege taxes. Transaction privilege taxes apply to the sale and are the responsibility of the seller to remit. Failure collect such taxes from the buyer does not relieve the seller from its obligation to remit taxes.
- 4.3.3 Tax Indemnification. Contractor and all subcontractors shall pay all Federal, state and local taxes applicable to its operation and any persons employed by the Contractor. Contractor shall, and require all subcontractors to hold the State harmless from any responsibility for taxes, damages and interest, if applicable, contributions required under Federal, and/or state and local laws and regulations and any other costs including transaction privilege taxes, unemployment compensation insurance, Social Security and Worker's Compensation.
- 4.3.4 IRS W9 Form. In order to receive payment the Contractor shall have a current IRS W9 Form on file with the State of Arizona, unless not required by law.
- 4.4 Availability of Funds for the Next State fiscal year. Funds may not presently be available for performance under this Contract beyond the current state fiscal year. No legal liability on the part of the State for any payment may arise under this Contract beyond the current state fiscal year until funds are made available for performance of this Contract.

## **UNIFORM TERMS AND CONDITIONS**

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4.5 Availability of Funds for the current State fiscal year. Should the State Legislature enter back into session and reduce the appropriations or for any reason and these goods or services are not funded, the State may take any of the following actions:

- 4.5.1 Accept a decrease in price offered by the, contractor
- 4.5.2 Cancel the Contract
- 4.5.3 Cancel the contract and re-solicit the requirements.

#### **5 Contract changes**

5.1 Amendments. This Contract is issued under the authority of the Procurement Officer who signed this Contract. The Contract may be modified only through a Contract Amendment within the scope of the Contract. Changes to the Contract, including the addition of work or materials, the revision of payment terms, or the substitution of work or materials, directed by a person who is not specifically authorized by the procurement officer in writing or made unilaterally by the Contractor are violations of the Contract and of applicable law. Such changes, including unauthorized written Contract Amendments shall be void and without effect, and the Contractor shall not be entitled to any claim under this Contract based on those changes.

5.2 Subcontracts. The Contractor shall not enter into any Subcontract under this Contract for the performance of this contract without the advance written approval of the Procurement Officer. The Contractor shall clearly list any proposed subcontractors and the subcontractor's proposed responsibilities. The Subcontract shall incorporate by reference the terms and conditions of this Contract.

5.3 Assignment and Delegation. The Contractor shall not assign any right nor delegate any duty under this Contract without the prior written approval of the Procurement Officer. The State shall not unreasonably withhold approval.

#### **6 Risk and Liability**

6.1 Risk of Loss. The Contractor shall bear all loss of conforming material covered under this Contract until received by authorized personnel at the location designated in the purchase order or Contract. Mere receipt does not constitute final acceptance. The risk of loss for nonconforming materials shall remain with the Contractor regardless of receipt.

6.2 Indemnification

6.2.1 Contractor/Vendor Indemnification (Not Public Agency) The parties to this contract agree that the State of Arizona, its' departments, agencies, boards and commissions shall be indemnified and held harmless by the contractor for the vicarious liability of the State as a result of entering into this contract. However, the parties further agree that the State of Arizona, its' departments, agencies, boards and commissions shall be responsible for its' own negligence. Each party to this contract is responsible for its' own negligence.

6.2.2 Public Agency Language Only Each party (as 'indemnitor') agrees to indemnify, defend, and hold harmless the other party (as 'indemnitee') from and against any and all claims, losses, liability, costs, or expenses (including reasonable attorney's fees) (hereinafter collectively referred to as 'claims') arising out of bodily injury of any person (including death) or property damage but only to the extent that such claims which result in vicarious/derivative liability to the indemnitee, are caused by the act, omission, negligence, misconduct, or other fault of the indemnitor, its' officers, officials, agents, employees, or volunteers."

6.3 Indemnification - Patent and Copyright. The Contractor shall indemnify and hold harmless the State against any liability, including costs and expenses, for infringement of any patent, trademark or copyright arising out of Contract performance or use by the State of materials furnished or work performed under this Contract. The State shall reasonably notify the Contractor of any claim for which it may be liable under this paragraph. If the contractor is insured pursuant to A.R.S. § 41-621 and § 35-154, this section shall not apply.



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#### 6.4 Force Majeure.

6.4.1 Except for payment of sums due, neither party shall be liable to the other nor deemed in default under this Contract if and to the extent that such party's performance of this Contract is prevented by reason of force majeure. The term "*force majeure*" means an occurrence that is beyond the control of the party affected and occurs without its fault or negligence. Without limiting the foregoing, force majeure includes acts of God; acts of the public enemy; war; riots; strikes; mobilization; labor disputes; civil disorders; fire; flood; lockouts; injunctions-intervention-acts; or failures or refusals to act by government authority; and other similar occurrences beyond the control of the party declaring force majeure which such party is unable to prevent by exercising reasonable diligence.

6.4.2 Force Majeure shall not include the following occurrences:

6.4.2.1 Late delivery of equipment or materials caused by congestion at a manufacturer's plant or elsewhere, or an oversold condition of the market;

6.4.2.2 Late performance by a subcontractor unless the delay arises out of a force majeure occurrence in accordance with this force majeure term and condition; or

6.4.2.3 Inability of either the Contractor or any subcontractor to acquire or maintain any required insurance, bonds, licenses or permits.

6.4.3 If either party is delayed at any time in the progress of the work by force majeure, the delayed party shall notify the other party in writing of such delay, as soon as is practicable and no later than the following working day, of the commencement thereof and shall specify the causes of such delay in such notice. Such notice shall be delivered or mailed certified return receipt and shall make a specific reference to this article, thereby invoking its provisions. The delayed party shall cause such delay to cease as soon as practicable and shall notify the other party in writing when it has done so. The time of completion shall be extended by Contract Amendment for a period of time equal to the time that results or effects of such delay prevent the delayed party from performing in accordance with this Contract.

6.4.4 Any delay or failure in performance by either party hereto shall not constitute default hereunder or give rise to any claim for damages or loss of anticipated profits if, and to the extent that such delay or failure is caused by force majeure.

6.5 Third Party Antitrust Violations. The Contractor assigns to the State any claim for overcharges resulting from antitrust violations to the extent that those violations concern materials or services supplied by third parties to the Contractor, toward fulfillment of this Contract.

## 7 Warranties

7.1 Liens. The Contractor warrants that the materials supplied under this Contract are free of liens and shall remain free of liens.

7.2 Quality. Unless otherwise modified elsewhere in these terms and conditions, the Contractor warrants that, for one year after acceptance by the State of the materials, they shall be:

7.2.1 Of a quality to pass without objection in the trade under the Contract description;

7.2.2 Fit for the intended purposes for which the materials are used;

7.2.3 Within the variations permitted by the Contract and are of even kind, quantity, and quality within each unit and among all units;

7.2.4 Adequately contained, packaged and marked as the Contract may require; and

7.2.5 Conform to the written promises or affirmations of fact made by the Contractor.

7.3 Fitness. The Contractor warrants that any material supplied to the State shall fully conform to all requirements of the Contract and all representations of the Contractor, and shall be fit for all purposes and uses required by the Contract.

## UNIFORM TERMS AND CONDITIONS

### SOLICITATION NO.: HP861156

- 7.4 Inspection/Testing. The warranties set forth in subparagraphs 7.1 through 7.3 of this paragraph are not affected by inspection or testing of or payment for the materials by the State.
- 7.5 Year 2000.
- 7.5.1 Notwithstanding any other warranty or disclaimer of warranty in this Contract, the Contractor warrants that all products delivered and all services rendered under this Contract shall comply in all respects to performance and delivery requirements of the specifications and shall not be adversely affected by any date-related data Year 2000 issues. This warranty shall survive the expiration or termination of this Contract. In addition, the defense of *force majeure* shall not apply to the Contractor's failure to perform specification requirements as a result of any date-related data Year 2000 issues.
- 7.5.2 Additionally, notwithstanding any other warranty or disclaimer of warranty in this Contract, the Contractor warrants that each hardware, software, and firmware product delivered under this Contract shall be able to accurately process date/time data (including but not limited to calculation, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000 and leap year calculations, to the extent that other information technology utilized by the State in combination with the information technology being acquired under this Contract properly exchanges date-time data with it. If this Contract requires that the information technology products being acquired perform as a system, or that the information technology products being acquired perform as a system in combination with other State information technology, then this warranty shall apply to the acquired products as a system. The remedies available to the State for breach of this warranty shall include, but shall not be limited to, repair and replacement of the information technology products delivered under this Contract. In addition, the defense of *force majeure* shall not apply to the failure of the Contractor to perform any specification requirements as a result of any date-related data Year 2000 issues.
- 7.6 Compliance With Applicable Laws. The materials and services supplied under this Contract shall comply with all applicable Federal, state and local laws, and the Contractor shall maintain all applicable licenses and permit requirements.
- 7.7 Survival of Rights and Obligations after Contract Expiration or Termination.
- 7.7.1 Contractor's Representations and Warranties. All representations and warranties made by the Contractor under this Contract shall survive the expiration or termination hereof. In addition, the parties hereto acknowledge that pursuant to A.R.S. § 12-510, except as provided in A.R.S. § 12-529, the State is not subject to or barred by any limitations of actions prescribed in A.R.S., Title 12, Chapter 5.
- 7.7.2 Purchase Orders. The Contractor shall, in accordance with all terms and conditions of the Contract, fully perform and shall be obligated to comply with all purchase orders received by the Contractor prior to the expiration or termination hereof, unless otherwise directed in writing by the Procurement Officer, including, without limitation, all purchase orders received prior to but not fully performed and satisfied at the expiration or termination of this Contract.
- 8 State's Contractual Remedies**
- 8.1 Right to Assurance. If the State in good faith has reason to believe that the Contractor does not intend to, or is unable to perform or continue performing under this Contract, the Procurement Officer may demand in writing that the Contractor give a written assurance of intent to perform. Failure by the Contractor to provide written assurance within the number of Days specified in the demand may, at the State's option, be the basis for terminating the Contract under the Uniform Terms and Conditions or other rights and remedies available by law or provided by the contract.
- 8.2 Stop Work Order.

## **UNIFORM TERMS AND CONDITIONS**

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- 8.2.1 The State may, at any time, by written order to the Contractor, require the Contractor to stop all or any part, of the work called for by this Contract for period(s) of days indicated by the State after the order is delivered to the Contractor. The order shall be specifically identified as a stop work order issued under this clause. Upon receipt of the order, the Contractor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage.
- 8.2.2 If a stop work order issued under this clause is canceled or the period of the order or any extension expires, the Contractor shall resume work. The Procurement Officer shall make an equitable adjustment in the delivery schedule or Contract price, or both, and the Contract shall be amended in writing accordingly.
- 8.3 Non-exclusive Remedies. The rights and the remedies of the State under this Contract are not exclusive.
- 8.4 Nonconforming Tender. Materials or services supplied under this Contract shall fully comply with the Contract. The delivery of materials or services or a portion of the materials or services that do not fully comply constitutes a breach of contract. On delivery of nonconforming materials or services, the State may terminate the Contract for default under applicable termination clauses in the Contract, exercise any of its rights and remedies under the Uniform Commercial Code, or pursue any other right or remedy available to it.
- 8.5 Right of Offset. The State shall be entitled to offset against any sums due the Contractor, any expenses or costs incurred by the State, or damages assessed by the State concerning the Contractor's non-conforming performance or failure to perform the Contract, including expenses, costs and damages described in the Uniform Terms and Conditions.

## **9 Contract Termination**

- 9.1 Cancellation for Conflict of Interest. Pursuant to A.R.S. § 38-511, the State may cancel this Contract within three (3) years after Contract execution without penalty or further obligation if any person significantly involved in initiating, negotiating, securing, drafting or creating the Contract on behalf of the State is or becomes at any time while the Contract or an extension of the Contract is in effect an employee of or a consultant to any other party to this Contract with respect to the subject matter of the Contract. The cancellation shall be effective when the Contractor receives written notice of the cancellation unless the notice specifies a later time. If the Contractor is a political subdivision of the State, it may also cancel this Contract as provided in A.R.S. § 38-511.
- 9.2 Gratuities. The State may, by written notice, terminate this Contract, in whole or in part, if the State determines that employment or a Gratuity was offered or made by the Contractor or a representative of the Contractor to any officer or employee of the State for the purpose of influencing the outcome of the procurement or securing the Contract, an amendment to the Contract, or favorable treatment concerning the Contract, including the making of any determination or decision about contract performance. The State, in addition to any other rights or remedies, shall be entitled to recover exemplary damages in the amount of three times the value of the Gratuity offered by the Contractor.
- 9.3 Suspension or Debarment. The State may, by written notice to the Contractor, immediately terminate this Contract if the State determines that the Contractor has been debarred, suspended or otherwise lawfully prohibited from participating in any public procurement activity, including but not limited to, being disapproved as a subcontractor of any public procurement unit or other governmental body. Submittal of an offer or execution of a contract shall attest that the contractor is not currently suspended or debarred. If the contractor becomes suspended or debarred, the contractor shall immediately notify the State.
- 9.4 Termination for Convenience. The State reserves the right to terminate the Contract, in whole or in part at any time, when in the best interests of the State without penalty or recourse. Upon receipt of the written notice, the Contractor shall stop all work, as directed in the notice, notify all subcontractors of the effective date of the termination and minimize all further costs to the State. In the event of termination under this paragraph, all documents, data and reports prepared by the Contractor under the Contract shall become

## **UNIFORM TERMS AND CONDITIONS**

### **SOLICITATION NO.: HP861156**

the property of and be delivered to the State upon demand. The Contractor shall be entitled to receive just and equitable compensation for work in progress, work completed and materials accepted before the effective date of the termination. The cost principles and procedures provided in A.A.C. R2-7-701 shall apply.

#### **9.5 Termination for Default.**

9.5.1 In addition to the rights reserved in the contract, the State may terminate the Contract in whole or in part due to the failure of the Contractor to comply with any term or condition of the Contract, to acquire and maintain all required insurance policies, bonds, licenses and permits, or to make satisfactory progress in performing the Contract. The Procurement Officer shall provide written notice of the termination and the reasons for it to the Contractor.

9.5.2 Upon termination under this paragraph, all goods, materials, documents, data and reports prepared by the Contractor under the Contract shall become the property of and be delivered to the State on demand.

9.5.3 The State may, upon termination of this Contract, procure, on terms and in the manner that it deems appropriate, materials or services to replace those under this Contract. The Contractor shall be liable to the State for any excess costs incurred by the State in procuring materials or services in substitution for those due from the Contractor.

9.6 Continuation of Performance Through Termination. The Contractor shall continue to perform, in accordance with the requirements of the Contract, up to the date of termination, as directed in the termination notice.

#### **10 Contract Claims**

All contract claims or controversies under this Contract shall be resolved according to A.R.S. Title 41, Chapter 23, Article 9, and rules adopted thereunder.

#### **11 Arbitration**

The parties to this Contract agree to resolve all disputes arising out of or relating to this contract through arbitration, after exhausting applicable administrative review, to the extent required by A.R.S. §12-1518, except as may be required by other applicable statutes.

#### **12 Comments Welcome**

The State Procurement Office periodically reviews the Uniform Terms and Conditions and welcomes any comments you may have. Please submit your comments to: State Procurement Administrator, State Procurement Office, 100 North 15<sup>th</sup> Avenue, Suite 104, Phoenix, Arizona, 85007.

# **SPECIAL TERMS AND CONDITIONS**

## **SOLICITATION NO.: HP861156**

**1. PURPOSE:**

Pursuant to provisions of the Arizona Procurement Code, A.R.S. 41-2501 Et Seq., the State of Arizona, Department of Health Services (ADHS) intends to establish a contract for the materials or services as listed herein.

**2. TERM OF CONTRACT:**

The term of the resultant contract shall commence on date of last signature and shall remain in effect for one year, unless terminated, canceled, or extended as otherwise provided herein.

**3. CONTRACT EXTENSIONS:**

By mutual written contract amendment, any resultant contract may be extended for supplemental periods of up to 12 months. The total contract term, including extensions, shall not exceed a total of five (5) years from the effective date of the contract.

**4. CONTRACT TYPE:**

☒ **Fixed Price**

**5. AUTHORIZATION FOR PROVISION OF SERVICES:**

Authorization for purchase of services under this contract shall be made only upon ADHS issuance of a Purchase Order that is signed by an authorized agent. The Purchase Order will indicate the contract number and the dollar amount of funds authorized. The Contractor shall only be authorized to perform services up to the amount on the Purchase Order. ADHS shall not have any legal obligation to pay for services in excess of the amount indicated on the Purchase Order. No further obligation for payment shall exist on behalf of ADHS unless **a)** the Purchase Order is changed or modified with an official ADHS Procurement Change Order, and/or **b)** an additional Purchase Order is issued for purchase of services under this contract.

**6. LICENSES:**

The Contractor shall maintain in current status, all federal, state and local licenses and/or permits required for the operation of the business conducted by the contractor.

**7. INFORMATION DISCLOSURE**

The Contractor shall establish and maintain procedures and controls that are acceptable to the state for the purpose of assuring that no information contained in its records or obtained from the state or from others in carrying out its functions under the contract shall be used or disclosed by it, its agents, officers, or employees, except as required to efficiently perform duties under the contract. Persons requesting such information should be referred to the state. The Contractor also agrees that any information pertaining to individual persons shall not be divulged other than to employees or officers of Contractor as needed for the performance of duties under the contract, unless otherwise agreed to in writing by the state.

**8. KEY PERSONNEL:**

It is essential that the contractor provide adequate experienced personnel, capable of and devoted to the successful accomplishment of work to be performed under this contract. The contractor must agree to

## SPECIAL TERMS AND CONDITIONS

### SOLICITATION NO.: HP861156

assign specific individuals to the key positions.

- a. The contractor agrees that, once assigned to work under this contract, key personnel shall not be removed or replaced without written notice to the state.
- b. If key personnel are not available for work under this contract for a continuous period exceeding thirty (30) calendar days, or are expected to devote substantially less effort to the work than initially anticipated, the contractor shall immediately notify the state, and shall, subject to the concurrence of the state, replace such personnel with personnel of substantially equal ability and qualifications.

#### 9. INDEMNIFICATION CLAUSE:

Contractor shall indemnify, defend, save and hold harmless the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as "Claims") for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property caused, or alleged to be caused, in whole or in part, by the negligent or willful acts or omissions of Contractor or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of such contractor to conform to any federal, state or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the parties that the Indemnitee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnitee, be indemnified by Contractor from and against any and all claims. It is agreed that Contractor will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable. In consideration of the award of this contract, the Contractor agrees to waive all rights of subrogation against the State of Arizona, its officers, officials, agents and employees for losses arising from the work performed by the Contractor for the State of Arizona.

*This indemnity shall not apply if the contractor or sub-contractor(s) is/are an agency, board, commission or university of the State of Arizona.*

#### 10. INSURANCE:

Contractor and subcontractors shall procure and maintain until all of their obligations have been discharged, including any warranty periods under this Contract, are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by the Contractor, his agents, representatives, employees or subcontractors.

The *insurance requirements* herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. The State of Arizona in no way warrants that the minimum limits contained herein are sufficient to protect the Contractor from liabilities that might arise out of the performance of the work under this contract by the Contractor, its agents, representatives, employees or subcontractors, and Contractor is free to purchase additional insurance.

- A. **MINIMUM SCOPE AND LIMITS OF INSURANCE:** Contractor shall provide coverage with limits of liability not less than those stated below.

1. **Commercial General Liability – Occurrence Form**

Policy shall include bodily injury, property damage, personal injury and broad form contractual liability coverage.

- General Aggregate \$2,000,000

## SPECIAL TERMS AND CONDITIONS

### SOLICITATION NO.: HP861156

- |  |             |
|--|-------------|
| • Products – Completed Operations Aggregate        | \$1,000,000 |
| • Personal and Advertising Injury                  | \$1,000,000 |
| • Blanket Contractual Liability – Written and Oral | \$1,000,000 |
| • Fire Legal Liability                             | \$ 50,000   |
| • Each Occurrence                                  | \$1,000,000 |

- a. The policy shall be endorsed to include the following additional insured language: ***“The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees shall be named as additional insureds with respect to liability arising out of the activities performed by or on behalf of the Contractor”.***
- b. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Contractor.

#### 2. Automobile Liability

Bodily Injury and Property Damage for any owned, hired, and/or non-owned vehicles used in the performance of this Contract.

Combined Single Limit (CSL)	\$1,000,000
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- a. The policy shall be endorsed to include the following additional insured language: ***“The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees shall be named as additional insureds with respect to liability arising out of the activities performed by or on behalf of the Contractor, involving automobiles owned, leased, hired or borrowed by the Contractor”.***

#### 3. Worker's Compensation and Employers' Liability

Workers' Compensation	Statutory
Employers' Liability	
Each Accident	\$ 500,000
Disease – Each Employee	\$ 500,000
Disease – Policy Limit	\$1,000,000

- a. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Contractor.
- b. This requirement shall not apply to: Separately, EACH contractor or subcontractor exempt under A.R.S. 23-901, AND when such contractor or subcontractor executes the appropriate waiver (Sole Proprietor/Independent Contractor) form.

#### 4. Professional Liability (Errors and Omissions Liability)

Each Claim	\$1,000,000
Annual Aggregate	\$2,000,000

- a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Contractor warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be

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maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.

- b. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Contractor.
- c. The policy shall cover professional misconduct or lack of ordinary skill for those positions defined in the Scope of Work of this contract.

B. **ADDITIONAL INSURANCE REQUIREMENTS:** The policies shall include, or be endorsed to include, the following provisions:

- 1. The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees wherever additional insured status is required such additional insured shall be covered to the full limits of liability purchased by the Contractor, even if those limits of liability are in excess of those required by this Contract.
- 2. The Contractor's insurance coverage shall be primary insurance with respect to all other available sources.
- 3. Coverage provided by the Contractor shall not be limited to the liability assumed under the indemnification provisions of this Contract.

C. **NOTICE OF CANCELLATION:** Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, or reduced in coverage or in limits except after thirty (30) days prior written notice has been given to the State of Arizona. Such notice shall be sent directly to **(Arizona Department of Health Services, Procurement Office, 1740 West Adams Street, Phoenix AZ 85007, Attention: Procurement Specialist)** and shall be sent by certified mail, return receipt requested.

D. **ACCEPTABILITY OF INSURERS:** Insurance is to be placed with duly licensed or approved non-admitted insurers in the state of Arizona with an "A.M. Best" rating of not less than A- VII. The State of Arizona in no way warrants that the above-required minimum insurer rating is sufficient to protect the Contractor from potential insurer insolvency.

E. **VERIFICATION OF COVERAGE:** Contractor shall furnish the State of Arizona with certificates of insurance (ACORD form or equivalent approved by the State of Arizona) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

All certificates and endorsements are to be received and approved by the State of Arizona before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract, or to provide evidence of renewal, is a material breach of contract.

All certificates required by this Contract shall be sent directly to **(Arizona Department of Health Services, Procurement Office, 1740 West Adams Street, Phoenix AZ 85007, Attention: Procurement Specialist)**. The State of Arizona project/contract number and project description shall be noted on the certificate of insurance. The State of Arizona reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time. **DO NOT SEND CERTIFICATES OF INSURANCE TO THE STATE OF ARIZONA'S RISK MANAGEMENT SECTION.**



## SPECIAL TERMS AND CONDITIONS

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- F. **SUBCONTRACTORS:** Contractors' certificate(s) shall include all subcontractors as insureds under its policies **or** Contractor shall furnish to the State of Arizona separate certificates and endorsements for each subcontractor. All coverages for subcontractors shall be subject to the minimum requirements identified above.
- G. **APPROVAL:** Any modification or variation from the *insurance requirements* in this Contract shall be made by the Department of Administration, Risk Management Section, whose decision shall be final. Such action shall not require a formal Contract amendment, but may be made by administrative action.
- H. **EXCEPTIONS:** In the event the Contractor or sub-contractor(s) is/are a public entity, then the Insurance Requirements shall not apply. Such public entity shall provide a Certificate of Self-Insurance. If the contractor or sub-contractor(s) is/are a State of Arizona agency, board, commission, or university, none of the above shall apply.

#### 11. **PRICE INCREASE (1 YEAR):**

The state may review a fully documented request for a price increase only after the contract has been in effect for one (1) year. A price increase adjustment shall only be considered at the time of a contract extension and shall be a factor in the extension review process. The ADHS Procurement Office shall determine whether the requested price increase or an alternate option is in the best interest of the state.

#### 12. **PAYMENT:**

The Contractor shall submit to ADHS, a monthly statement of charges for the work completed under an approved project assignment in conformance with the pricing schedule of this contract. ADHS shall process the claim for prompt payment in accordance with the standard operating procedures of the state.

#### 13. **NON-EXCLUSIVE CONTRACT:**

The state reserves the right to obtain like goods or services from another source when necessary. Approval of other sources shall be at the exclusive discretion of the ADHS procurement administrator and shall be final. However, approval shall be granted only after a proper review and when deemed to be appropriate.

#### 14. **PUBLICATION OF DESCRIPTIVE LITERATURE OR MATERIALS:**

The Contractor shall request authorization from ADHS prior to publication of any materials related to or paid for under this contract.

#### 15. **OTHER CONTRACTS:**

The agency may undertake or award other Contracts for additional or related work and the Contractor shall fully cooperate with such other Contractors and state employees and carefully fit his own work to such additional work. The Contractor shall not commit or permit any act that will interfere with the performance of work by any other Contractor or by state employees. The agency shall equitably enforce this section as to all Contractors, to prevent the imposition of unreasonable burdens on any Contractor.

#### 16. **FINANCIAL MANAGEMENT:**

For all contracts, the practices, procedures, and standards specified in and required by the Accounting and Auditing Procedures Manual for Arizona Department of Health Services funded programs shall be used by the Contractor in the management of contract funds and by the Department when performing a contract audit. Funds collected by the Contractor in the form of fees, donations and/or charges for the delivery of

## **SPECIAL TERMS AND CONDITIONS**

### **SOLICITATION NO.: HP861156**

these contract services shall be accounted for in a separate fund.

State Funding. Contractors receiving state funds under this contract shall comply with the certified Compliance provisions of A.R.S. § 35-181.03.

Federal Funding. Contractors receiving federal funds under this contract shall comply with the certified finance and compliance audit provision of the Office of Management and Budget (OMB) Circular A-122 and/or A-133, if applicable. The federal financial assistance information shall be stated in a Change Order or Purchase Order.

#### **17. VOLUME OF WORK:**

The Arizona Department of Health Services does not guarantee a specific amount of work either for the life of the contract or on an annual basis.

#### **18. RESTRICTION FOR USE OF FUNDS:**

- A. Funds shall not be used for expenditures on capital construction projects, lobbying activities involving elected officials or political campaigns for individuals or any ballot proposals.
- B. Funds shall not be used to supplant other funds being used to provide covered services.

#### **19. INSPECTION AND ACCEPTANCE:**

All services, data and required reports are subject to final inspection, review, evaluation and acceptance by ADHS. ADHS may withhold payment for services that are deemed not to meet contract standards.

#### **20. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA):**

The Contractor warrants that it is familiar with the requirements of HIPAA and HIPAA's accompanying regulations and shall comply with all applicable HIPAA requirements in the course of this contract. Contractor warrants that it shall cooperate with the Arizona Department of Health Services (ADHS) in the course of performance of the contract so that both the ADHS and Contractor shall be in compliance with HIPAA, including cooperation and coordination with the ADHS Privacy Officer and other compliance officials required by HIPAA and its regulations. Contractor shall sign any documents that are reasonably necessary to keep the ADHS and Contractor in compliance with HIPAA, including, but not limited to, business associate agreements.

If requested by the ADHS, Contractor agrees to sign the "Arizona Department of Health Services Pledge To Protect Confidential Information" and to abide by the statements addressing the creation, use and disclosure of confidential information, including information designated as protected health information and all other confidential or sensitive information as defined in policy. In addition, if requested, Contractor agrees to attend or participate in HIPAA training offered by the ADHS or to provide written verification that the Contractor has attended or participated in job related HIPAA training that is: (1) intended to make the Contractor proficient in HIPAA for purposes of performing the services required and (2) presented by a HIPAA Privacy Officer or other person or program knowledgeable and experienced in HIPAA and who has been approved by the ADHS HIPAA Compliance Officer.

#### **21. OFFSHORE PERFORMANCE OF WORK PROHIBITED:**

Due to security and identity protection concerns, direct services under this contract shall be performed within the borders of the United States. Any services that are described in the specifications or scope of

## **SPECIAL TERMS AND CONDITIONS**

### **SOLICITATION NO.: HP861156**

work that directly serve the State of Arizona or its clients and may involve access to secure or sensitive data or personal client data or development or modification of software for the State shall be performed within the borders of the United States. Unless specifically stated otherwise in the specifications, this definition does not apply to indirect or "overhead" services, redundant back-up services or services that are incidental to the performance of the contract. This provision applies to work performed by subcontractors at all tiers.

#### **22. FEDERAL IMMIGRATION AND NATIONALITY ACT:**

By entering into the Contract, the Contractor warrants compliance with the Federal Immigration and Nationality Act (FINA) and all other Federal immigration laws and regulations related to the immigration status of its employees. The Contractor shall obtain statements from its subcontractors certifying compliance and shall furnish the statements to the Procurement Officer upon request. These warranties shall remain in effect through the term of the Contract. The Contractor and its subcontractors shall also maintain Employment Eligibility Verification forms (I-9) as required by the U.S. Department of Labor's Immigration and Control Act, for all employees performing work under the Contract. I-9 forms are available for download at USCIS.GOV

The State may request verification of compliance for any Contractor or subcontractor performing work under the Contract. Should the State suspect or find that the Contractor or any of its subcontractors are not in compliance, the State may pursue any and all remedies allowed by law, including, but not limited to: suspension of work, termination of the Contract for default, and suspension and/or debarment of the Contractor. All costs necessary to verify compliance are the responsibility of the Contractor.

#### **23. INCORPORATION BY REFERENCE**

The subject solicitation, including the Uniform Instructions to the Offerors, the specifications and Statement or Scope of Work, any amendments thereto, and the Contractor's proposal including additional clarification and response, best and final offeror, its appendices and attachments, including any approved Subcontracts are hereby incorporated by reference as being part of this Contract as provided herein.

#### **24. BID BOND**

- A. An irrevocable bid security payable to the State of Arizona in the amount of 20% of the total annual bid price is required. This security shall be in the form of a bid bond, certified check or cashier's check and must be in the possession of the state by the due time and date cited for this solicitation.
- B. The state will hold all bid security during the evaluation process. As soon as is practicable after the completion of the evaluation, the state will:
  - 1. Issue an award notice for those offers accepted by the State; and
  - 2. Return all bond securities to those who have not been issued an award notice.
- C. All bid security from contractors who have been issued an award notice shall be held until the successful execution of all required contractual documents and bonds (performance bond, insurance, etc.). If the contractor fails to execute the required contractual documents and bonds within the time specified, or ten (10) days after notice of award if no period is specified, the contractor may be found to be in default and the contract terminated by the state. In case of default, the state reserves all rights inclusive of, but not limited to, the right to purchase material and/or complete the work as required, in accordance with the Arizona Procurement Code and to recover any actual excess costs from the contractor. Collection against the bid security shall be one of the measures available toward the recovery of any excess costs.
- D. All bid bonds must be executed on forms substantially equivalent to the form included with this solicitation.

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*This bid security shall not be required if the contractor or sub-contractor(s) is/are an agency, board, commission or university of the State of Arizona.*

#### **25. PERFORMANCE BOND:**

- A. The contractor shall be required to furnish an irrevocable security in the amount of \$400,000.00 of the total contract price payable to the State of Arizona, binding the contractor to provide faithful performance of the contract.
- B. Performance security shall be in the form of a performance bond, certified check or cashier's check. This security must be in the possession of the state within ten (10) calendar days from receipt of notice of award. If the contractor fails to execute the security document, as required, the contractor may be found in default and contract terminated by the state. In case of default, the state reserves all rights to recover as provided by law.
- C. All performance bonds must be executed on forms substantially equivalent to the form included with this solicitation.'

*This security shall not be required if the contractor or sub-contractor(s) is/are an agency, board, commission or university of the State of Arizona*

#### **26. LICENSURE AND CERTIFICATION REQUIREMENTS**

- A. All of the Contractor's laboratory personnel shall be licensed and certified according to Clinical Laboratory Improvement Act (CLIA) 88 regulations for High Complexity Testing (Federal Register, Vol. 57, No. 49, 2/28/92).
- B. All of the Contractor's laboratory facilities shall be licensed by the appropriate state licensing authority and is certified by CLIA. The facility shall continue to be licensed by the above throughout the life of a resultant contract.
- C. The Contractor's Screening Laboratory Director shall be a doctoral level prepared (M.D./D.O./Ph.D.) individual whose qualifications meet CLIA 88 regulations for "High Complexity Testing". Any individual holding this position during the life of a resultant contract shall meet the above-mentioned requirements.

#### **27. ADDITIONAL TESTING**

ADHS reserves the right to add more tests for congenital disorders. If these tests can be performed with the Tandem Mass Spectrometry, Immunoassay, High Performance Liquid Chromatography, and deoxyribonucleic acid (DNA) analysis instruments, then the Contractor may charge for the additional tests at the current contract rate for specimen testing. If the additional tests require a different testing method, then the Contractor shall provide detailed financial justification for the cost of performing the tests. ADHS will negotiate in good faith a rate acceptable to ADHS and the Contractor.

#### **28. EXPANDED TESTING**

ADHS understands that there may be interest in performing additional tests and/or studies on the blood specimens beyond what is required by this Contract. ADHS also understands that there may be monetary value in conducting additional testing and in the information it provides.

After the Contract is awarded and to the extent permitted by law, if the Contractor is interested in performing tests and/or studies on the blood specimens, the Contractor may submit a written request to do so. The request shall include a detailed description of the test and studies to be performed, whether the

<p style="text-align: center;"><b>SPECIAL TERMS AND CONDITIONS</b> <b>SOLICITATION NO.: HP861156</b></p>
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research has been approved by an Institutional Review Board if necessary, why the request is being made, the monetary value to the Contractor and how much the Contractor will discount the current Contract rate for testing because of the monetary value for being allowed to perform additional testing. Contractor shall also submit any additional information that ADHS deems necessary.

ADHS is under no obligation to approve any requests by the Contractor to perform tests and/or studies on the blood specimens beyond what the Contract requires. Any approval to perform additional tests and/or studies on the blood specimens shall be in the form of a contract amendment negotiated by the parties.

# SCOPE OF WORK

## SOLICITATION NO.: HP861156

### I. OBJECTIVE

The Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health, Office of Newborn Screening (ONBS) is soliciting proposals in order to establish a contract for newborn screening clinical laboratory services, technical laboratory assistance and educational services to specimen submitters and program support. In accordance with A.R.S. §36-694, section I, proposals may be accepted from hospitals, clinical laboratories licensed pursuant to A.R.S. §36-461 to 36-479, the state laboratory (the ADHS State Laboratory) described in A.R.S. §36-251, and any other qualified public or private persons.

ADHS requires a total solution to newborn screening clinical laboratory services. The Contractor shall be responsible for supplying all equipment, materials, supplies, personnel, labor and facilities in performing the services required by the Scope of Work. Services shall be performed at the Contractors facilities.

### II. BACKGROUND

For many types of congenital disorders of a genetic or endocrine nature, early diagnosis and treatment is critical. Although babies born with these disorders may appear to be normal at birth, with time the disorder may have a devastating or lethal effect on the infant's brain and other organ systems. Early screening, detection and treatment of these disorders can, in most cases, result in much improved growth and development.

Arizona began conducting widespread newborn screening for certain types of genetic disorders in 1979. In 1993, the Arizona Legislature enacted legislation requiring the ADHS to develop and administer a formal Newborn Screening Program. This legislature afforded ADHS with the opportunity to obtain more timely results from screening, and promote better follow-up for suspected or confirmed cases of screened disorders. In April 2005, further legislation was enacted requiring ADHS to specify in rule the disorders, the process for collecting and submitting specimens, and reporting requirements for test results (A.R.S. §36-694, <http://www.azleg.gov/FormatDocument.asp?inDoc=/ars/36/00694.htm&Title=36&DocType=ARS>).

#### **Components of the New Born Screening Program include:**

**Healthcare Providers and Submitters** – The attending physician or person who is required to make a report on the birth is responsible for ordering the collection of the newborn screen (Arizona Revised Statute §36-694 et al), informing the newborn's parents about the screen, and promptly following up with families in the event of an abnormal screen. The agency ordered to collect the specimen may be a hospital, healthcare provider office, or laboratory (Submitter). The Submitter is responsible for the collection, labeling, handling, and submission of the specimen to the Screening Laboratory. Healthcare Providers and Submitters work together to coordinate timely collection and delivery of acceptable newborn screen specimens to the contracted Laboratory.

**Screening Laboratory (Contractor)** - The Screening Laboratory receives newborn screening specimens collected throughout Arizona in order to test for screened congenital disorders. The Laboratory reviews the specimens for acceptability, performs the screening tests, keeps records of the tests performed, conducts quality control studies of laboratory methods and practices, and conducts single disorder repeat tests ordered in response to an abnormal result on a previous screening test and dietary monitoring tests for phenylalanine. The Laboratory also reports screening results to Follow-up Staff of the ONBS and to healthcare providers and agencies ordering and submitting specimens. The Laboratory bills submitters, insurers, or responsible parties for the tests performed.

**Data Management System** - The ADHS ONBS currently utilizes software from Neometrics, a Division of Natus, for newborn screening data management. The Neometrics system has the capacity to load, store, and retrieve data as well as automate many administrative tasks necessary to operate the ONBS. The Neometrics system has two primary components, one for laboratory functions and one for case management functions.

The laboratory component (Metabolic Screening Database System – MSDS) allows laboratory personnel to enter newborn demographic information obtained from specimens, track specimens received, record screen test results associated with each specimen tested, produce results mailers, and report data to be used for invoices.

## **SCOPE OF WORK**

### **SOLICITATION NO.: HP861156**

Abnormal screen test results are electronically transmitted to the case management component of Neometrics. Data transfer to this component allows triggering and tracking of ongoing services by the ONBS Follow-up staff and generation of letters and reports.

**Program Administration** - The Arizona Department of Health Services ONBS Chief is responsible for the administration and coordination of program operations, monitoring the performance of the contracted laboratory, monitoring revenue from the screening fee collections, and coordinating resource networks for the specialized treatment and medical management of disorders identified through newborn screening.

The ONBS Chief also administers the follow-up component of newborn screening. Follow-up staff responsibilities include: reporting positive results to physicians and parents; tracking infants with positive results to obtain appropriate care; monitoring and evaluating the system; monitoring confirmatory testing; and maintaining a registry of confirmed cases.

### **III. MANDATORY SERVICE REQUIREMENTS**

- A. The Contractor shall have at least five years of experience in providing newborn screening clinical laboratory services within the past ten years.
- B. All the Contractor's laboratory personnel shall be licensed and certified according to Clinical Laboratory Improvement Act (CLIA) 88 regulations for "High Complexity Laboratory Testing" (Federal Register, Vol 57, No. 49, 2/28/92).
- C. All the Contractor's laboratory facilities shall be licensed by the appropriate state licensing authority and is certified by CLIA.
- D. The Contractor's Screening Laboratory Director shall be a doctoral level prepared (M.D./D.O./Ph.D.) individual whose qualifications meet CLIA 88 regulations for "High Complexity Testing".
- E. Maintain at all times the ability and capability to perform laboratory testing using Tandem Mass Spectrometry, Immunoassay, High Performance Liquid Chromatography, and deoxyribonucleic acid (DNA) analysis instruments.

### **IV. SCOPE OF SERVICES**

The Contractor shall provide clinical laboratory services for the ADHS ONBS, primarily conducting laboratory tests on specimens of human origin that may aid in the diagnosis, treatment, and prevention of disease starting August 1, 2008. Clinical laboratory services also include the receipt, tracking, testing, results notification, and billing for all Arizona Newborn Screening specimens collected for testing, as well as providing and distributing screening collection kits and shipping/mailling of specimens from the submitter to Contractor.

The Contractor shall review the specimens for acceptability, perform the screening tests, keep records of the tests performed, and conduct quality control studies of laboratory methods and practices, in accordance with national standards and Newborn Screening Program protocols. The Contractor shall also perform single disorder repeat tests ordered in response to an abnormal result on a previous screen, phenylalanine tests for dietary monitoring, and report results to Follow-up staff of the ONBS and to Submitters and Healthcare Providers of record.

The Contractor shall bill the responsible party for the testing as defined in Arizona Administrative Code R9-13-201 et seq. and provide financial reports to the ADHS ONBS.

The Contractor shall also provide technical assistance, education services to submitters, and program support to the ONBS. Technical and programmatic support pertains to coordination, consultation, education, technical assistance and technical support activities provided for or on behalf of the ONBS.

### **V. REQUIRED TASKS**

## **SCOPE OF WORK**

### **SOLICITATION NO.: HP861156**

The Contractor shall provide the following clinical laboratory services and comply with all policies, procedures, and protocols established for the Newborn Screening Program per the following references:

1. Newborn Screening Guidelines;
2. Description of Newborn Screening Program;
3. Arizona Revised Statute A.R.S. §36-694 et al, §36-2327 et al, §20-2327 et al, §12-2802 et al and §12-2803 et al; and
4. Arizona Administrative Code R9-13-101 to R9-13-1503 and R9-14-101 to R9-14-709.

A. Project Manager - Provide a Project Manager who shall be the primary contact person for the ADHS Contract Administrator in discussing work that needs to be done. The Project Manager shall, at a minimum:

1. Serve as a primary day-to-day contact with the Agency;
2. Attend, lead, and prepare materials for meetings as requested;
3. Ensure all necessary operational components are completed prior to implementation;
4. Troubleshoot and correct problems after implementation; and
5. Designate an alternate contact for when the Project Manager is unavailable.

B. Specimen Collection Kit (filter paper kit) Printing and Distribution - The Contractor shall provide and ship filter paper collection kits to all hospitals delivering newborns in Arizona and to providers who request kits. The Contractor shall also provide for transport of collected specimens to the laboratory within 24 hours of specimen collection. The ADHS utilizes linked specimen collection kits and single use kits. The kit is used to record information about the newborn and specimen collection as well as absorb the newborn's blood specimen in specially fabricated filter paper. The linked kits consist of two attached kits with a linked numbering system, to facilitate matching of initial and second screening specimens. One of the kits is used when the initial specimen is taken; the linked kit is given to the parent to take to a doctor, laboratory or county health department to be used when the second specimen is collected. The single use kits are not linked, and are reserved for use in instances where the linked kit was lost or damaged, or for other reasons. The Contractor shall:

1. Utilize the specimen collection kit approved for use by the ONBS. As part of the kit, the Contractor shall only use filter paper approved for newborn screening, and shall print collection kits which are in compliance with standards set by the American Public Health Laboratories Association ([www.aphl.org](http://www.aphl.org)).
2. Participate with ONBS representatives in making changes or modifications to the specimen collection kits used for newborn bloodspot screening in Arizona. The ONBS shall approve the design and quality of the specimen collection kits, and shall approve any proposed changes or modifications to the kit prior to implementation.
3. Print a sufficient number of specimen collection kits on an annual basis to ensure that there is an adequate supply of these kits to meet all newborn screening test needs and requirements.
4. Implement a distribution and tracking system for the kits, and ensure that there are sufficient specimen collection kits available for shipment at all times.
5. Ship specimen collection kits to all hospitals delivering newborns in Arizona as needed.
6. Utilize collection kit and specimen transportation methods that minimize the possible effects of irradiation, heat and humidity or moisture on the specimen.

C. Specimen Receipt, Logging And Tracking - The Contractor shall use Neometrics MSDS software compatible with the ADHS Neometrics software for the receipt, logging, and tracking of all newborn screening specimens and



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all other specimen specific activities, or cause all specimen data activities as above to be transferred into the ADHS Neometrics software. The Contractor shall maintain a database capable of reporting screen results with more than one result element per disorder in such a manner that the ADHS may access test results and demographic information and export necessary fields to a case management module as soon as laboratory results are entered.

The Contractor's receipt, logging and tracking of specimens shall include the following activities, at a minimum:

1. Use written procedures for receipt and logging of newborn screen specimens that comply with United States Health and Human Services Clinical Laboratory Improvement Amendments (CLIA) requirements.
2. Enter all data received from each filter paper kit into the Neometrics database. Demographic data shall be entered whether or not the specimen is testable. The Contractor shall comply with all policies and protocols established by the ONBS for the use and maintenance of the Neometrics system, or other system procured or adopted by the ADHS for the ONBS.
3. Track all specimens received, and accurately reflect the status of the receipt and analysis of each specimen.
4. Identify and immediately notify the healthcare provider and submitter of unsatisfactory specimens unable to be tested.
5. Contact the Submitter to obtain the corrected or missing information when demographic patient information is absent or inconsistent on the specimen. The Contractor shall monitor the quality of demographic data provided by submitters. The Contractor shall contact submitters to correct trends of inaccurate or incomplete demographic data submission.
6. Use written procedures for the acceptance and rejection of Newborn Screening specimens. Procedures must comply with A.A.C. R9-13-203 and be approved by the ONBS.
7. In the case of an unsatisfactory newborn screening specimen, the Contractor shall notify the Submitter by telephone within 24 hours of receipt of the unsatisfactory specimen of the need to rescreen the newborn. Following telephone notification, the Contractor shall notify the Submitter in writing within 72 hours of receipt of the specimen of the need to rescreen, including the reason the specimen could not be tested.
8. Provide the original bloodspot specimen and demographics card or full visual display of the specimen and demographic card to the ONBS as needed and within one hour of a request by the ONBS.
9. Provide original bloodspot specimens as requested by the ONBS within 48 hours of request.
10. Request technical assistance from Neometrics for software problems and the Contractor's Information Technology Services department for hardware problems. Problems that impede the Contractor's ability to perform the contracted tasks shall also be reported to the ONBS Chief.
11. Only conduct tests or studies within the scope of this contract on the blood specimens submitted for newborn screening. Any other testing may not be performed without prior written authorization of ADHS.
12. Maintain specimens following procedures approved by the ONBS. Specimens and leftover samples shall be stored for 90 days then destroyed following procedures approved by the ONBS. The Contractor shall not utilize, provide for utilization, or store for future use any specimens or leftover samples covered under the provisions of this contract for external activities and/or partnerships without prior written authorization of the ONBS. No deviation from the approved procedure may be taken without prior authorization of the ONBS.
13. Necessary testing of submitted newborn specimens at external laboratories for the purpose of laboratory testing validation shall be the responsibility of the Contractor after written authorization is

## **SCOPE OF WORK**

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obtained from the ONBS. Specimen testing at external laboratories for diagnostic confirmation shall be directed to the party responsible for the newborn's care.

D. Laboratory Analysis, Interpretation, and Reporting of Test Results - The Contractor shall perform laboratory tests on dried blood spot specimens, interpret results, and report results. The Contractor shall perform laboratory tests using CLIA compliant laboratory practices, and testing methods and parameters approved by the ONBS. Laboratory tests shall be performed to screen for the following disorders:

1. Congenital Hypothyroidism
2. Phenylketonuria
3. Galactosemia
4. Homocystinuria
5. Maple Syrup Urine Disease
6. Biotinidase Deficiency
7. Sickle cell anemia
8. Hb S/Beta-Thalassemia
9. Hb S/C disease
10. Congenital Adrenal Hyperplasia
11. Citrullinemia
12. Argininosuccinic acidemia
13. Tyrosinemia type I
14. Isovaleric acidemia
15. Glutaric acidemia type I
16. Hydroxymethylglutaric aciduria
17. Multiple carboxylase deficiency
18. Methylmalonic acidemia due to mutase deficiency
19. Methylmalonic acidemia cblA and cblB forms
20. 3-Methylcrotonyl-CoA carboxylase deficiency
21. Propionic acidemia
22. Beta-Ketothiolase deficiency
23. Medium-chain acyl-CoA dehydrogenase deficiency
24. Very long-chain acyl-CoA dehydrogenase deficiency
25. Long-chain 3-OH acyl-CoA dehydrogenase deficiency
26. Trifunctional protein deficiency
27. Carnitine uptake defect
28. Cystic Fibrosis (two tier testing using immunoreactive trypsinogen with at least 2.2% of each day's specimens with the highest results additionally tested for direct cystic fibrosis transmembrane conductance regulator gene analysis of over 40 mutations likely to be found in Arizona's newborn population and as approved by the ONBS)

E. Validity Testing - The Contractor shall test all laboratory methodologies, first authorized by the ONBS Chief, with sufficient parallel or other type of testing to ensure the validity of the methodology. Values determined by studies to establish the accuracy of testing and the limits found to positively or negatively predict presence of disorder shall be provided to the ONBS. Cut-off levels shall be established to provide maximum specificity and sensitivity and must be approved by the ONBS.

F. New Testing - Preparation for testing of new disorders approved by the ONBS Chief, shall include sufficient pilot testing to establish the acceptable limits for presumptive positive, borderline, and negative screening results. Data demonstrating this pilot testing shall be provided to the ONBS.

G. Performance Requirements - The Contractor's performance of newborn screening laboratory tests, analysis, interpretation, and reporting of test results for newborn screening must conform to the following requirements:

1. Compliance with policies, procedures, and protocols established for the ONBS for the analysis, interpretation, and reporting of positive test results, as provided by the ONBS.
2. Test results must be entered into the Neometrics database system or electronically transferred into the

## **SCOPE OF WORK**

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Neometrics database system from laboratory instruments.

3. Laboratory tests must be performed utilizing CLIA compliant practices.
4. The Contractor must specify the analytical methodology and instruments used, including those used for back up or confirmation.
5. At least ninety-five percent of newborn screening specimens must be processed and results mailed to providers and submitters within three days of receipt of the specimen. The remaining specimens must be processed and results mailed to providers and submitters within seven days of receipt of the specimen.
6. All newborn screening results with other than normal results must be electronically tagged for transfer to the case management component of the Neometrics database immediately upon release of the specimen result.
7. Specimens determined to have a presumptive positive (highly abnormal) result for at least one of the screened disorders shall be reported immediately upon Laboratory finding via telephone or in person to the Follow-up Coordinator of the ONBS, with concurrent entry of the data into the Neometrics system and/or email or facsimile confirmation to the Follow-up Coordinator.
8. The Contractor shall notify the ONBS Chief by telephone of problems including but not limited to equipment, maintenance, subcontractor performance, and any other issues that may impede the ability of the Contractor to perform contracted service or affect the quality of contract service performance.
9. The Contractor shall provide annually updated written laboratory testing policies and procedures upon contract award and immediately following procedure changes. The policies and procedures document specific steps, timing, and resources (personnel and equipment) utilized in the analysis of a screening specimen from the receipt of filter paper kits, through the reporting of results to submitters (the collection source), to the storage, release and destruction of specimens.
10. The Contractor shall provide a Business Continuity and Disaster Recovery Plan to the ONSB upon initiation of contract year for uninterrupted full service provision in the event of disaster or circumstances prohibiting use of the Contractor's laboratory or reporting mechanisms for 48 hours or longer.
11. Newborn screening test results shall be securely and confidentially stored for six years in such a manner that the ADHS is able to retrieve, view and obtain paper copies without cost. At six years after the year of testing, the test result records shall be destroyed.

H. Quality Assurance and Improvement - The Contractor shall have a Quality Assurance and Improvement Plan approved by ADHS prior to receiving any specimens for testing. The Contractor shall design and implement a laboratory quality assurance and improvement program to assure the reliability of all laboratory results and contract compliance.

1. The Contractor shall have a written quality assurance (QA) and improvement plan that is reviewed and revised at least annually by the Contractor. The quality assurance plan shall incorporate information from all areas of operations to continuously improve the quality of clinical laboratory services, as well as education, technical assistance, program support, and all aspects of service in quality management and improvement processes. The Plan shall include an evaluation of the effectiveness of the prior year's quality improvement program and shall integrate what is learned through this evaluation into the upcoming Plan. The Contractor shall submit the quality assurance and improvement plan to the ADHS ONBS prior to receiving specimens for testing and annually thereafter.
2. The Contractor shall have an internal laboratory quality assurance committee that meets at least quarterly.
3. The Contractor shall collaborate at least quarterly and as requested with the ADHS ONBS to review presumptive positive results.

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4. Written policies and procedures for newborn screening laboratory services shall be maintained and updated in accordance with CLIA regulations.

5. The Contractor shall collaborate with the ONBS in the development of monitoring and follow-up procedures for unsatisfactory specimens. The ONBS shall have final approval of all changes to procedures and criteria.

6. The Contractor shall include monitoring and follow-up procedures to assure the accurate and timely entry of demographic information associated with specimens.

7. The Contractor shall maintain and enforce criteria for specimen rejection and for corrective action/training at specimen collection centers (submitter locations). Criteria must be CLIA compliant.

8. Upon determination by the ONBS to change or add new laboratory methodology in newborn screening, the Contractor shall implement the changes within the timeframe agreed upon by the ONBS and Contractor.

9. The Contractor must participate in the Newborn Screening Quality Assurance Program offered by the Centers for Disease Control and Prevention, Division of Laboratory Sciences. All quality assurance, quality control and proficiency testing programs and systems for each tested analyte shall be described in the quality assurance plan. Quality control, quality assurance and proficiency testing activities and outcomes shall be reported to the ONBS Chief.

I. Billing for Newborn Screening Laboratory Tests - The Contractor shall mail or electronically submit invoices to the responsible payer as defined in Rule (A.A.C. R9-13-203) to collect fees for laboratory screening tests.

1. The Contractor shall specify its methods and procedures for providing and evaluating billing services in writing annually and upon any procedural changes. Methods and procedures for billing services must be approved by the ONBS prior to implementation.

2. The Contractor shall prepare and send an invoice for all first newborn screens to the submitting hospital, midwife or birth center on a monthly basis by the 15<sup>th</sup> day after the service month, including each newborn's name and date of birth. The Contractor shall prepare and send an invoice for all second screens to the patient's insurer or responsible party within 30 days of mailing specimen results. If the submitter has not included sufficient information to prepare an invoice, the Contractor shall obtain the necessary information from the submitter or provider.

3. Postage and delivery, and third party billing expenses are the responsibility of the Contractor. The Contractor shall bill the following amounts for services:

- a. First screens - \$30 per screen;
- b. Second screens - \$40 per screen;
- c. Repeat test - no charge; and
- d. Dietary monitoring test – no charge.

4. The Contractor shall prepare and mail or electronically submit invoices to submitters. Payments from submitters shall be sent to:

Arizona Department of Health Services  
Newborn Screening Program  
PO Box 25046  
Phoenix, Arizona 85002-5046

5. The Contractor shall electronically submit a Billing Report to ADHS Accounting, summarizing the amounts billed to each payer monthly within 60 days of billing.

## **SCOPE OF WORK**

### **SOLICITATION NO.: HP861156**

6. In response to, and within 10 business days of receipt of, the Accounting Report provided monthly by the ADHS Accounting, the Contractor shall send a second invoice to the payer if a payment was not received within 30 days of the invoice date. The Contractor shall submit a report monthly summarizing outstanding balances, detailed by payer.

7. If there is a discrepancy between the amount billed and the amount received by ADHS from a hospital payer, the Contractor shall attempt to reconcile the discrepancy, utilizing the Neometrics system to verify and clarify numbers and types of screens tested. If the Contractor is unable to reconcile the discrepancy, ADHS Accounting, supported by the ONBS Chief, shall assist in this effort.

8. If an insurance carrier denies a claim, the Contractor shall investigate the claim and determine if the fee should be collectible from the insurance carrier. If the fee is considered collectible, the corrected claim shall be resubmitted within the time frame established by the insurer as payable. If not collectible, the Contractor shall submit an invoice to the responsible party within 30 days of insurance denial. If the responsible party does not submit payment within 30 days, the ADHS Accounting will request determination by the ADHS Business and Finance Division if the invoice qualifies to be adjusted off.

J. Technical Assistance and Quality Improvement Consultation - The Contractor shall provide technical assistance and quality improvement consultation to submitters regarding specimen collection and submission procedures for newborn screening tests. It shall be the Contractor's responsibility to ensure all submitters are adequately informed so that specimens are accurately collected and submitted. Submitter education and training activities are recognized as an integral part of the ONBS. The Contractor shall provide technical assistance in response to inquiries from hospitals, clinics, laboratories, ADHS and other interested parties regarding specimen collection and submission procedures for newborn screening tests. As a result of its quality assurance findings, the Contractor shall identify submitters not correctly submitting specimens and initiate contact with such submitters to provide technical assistance as appropriate. In addition, the Contractor shall collaborate with the ONBS in the design, implementation, and performance of educational offerings for submitters.

K. Newborn Screening Program Educational Services - The Contractor shall collaborate with the ONBS in the design, implementation, and evaluation of educational programs regarding newborn screening specimen collection and submittal. The ONBS Chief and/or Education/Quality Manager shall approve the content and format of any formal programs presented by the Contractor. Topics presented by the Contractor in educational offerings shall comply with ONBS policies and procedures, and include:

1. Proper usage of specimen collection kits (filter paper kits);
2. Proper blood collection technique;
3. Proper specimen packaging and shipping as outlined in the U.S. Department of Health and Human Services' "Guideline for the Shipment of Dried Blood Spot Specimens";
4. Proper laboratory procedures;
5. Fees assessed and the methods for collection and submittal of fees; and
6. Reports issued.

L. The Contractor shall collaborate with the ONBS to ensure that all Submitters have access to approved screening resources. The Contractor shall also collaborate with the ONBS in the periodic review and revision of specimen collection and submittal resource materials.

M. The Contractor shall collaborate with the ONBS to prepare a periodic informational letter to be mailed by the ONBS to submitters of newborn screening tests. The Contractor may publish generic quality management and monitoring information for use in improving quality and timeliness of specimen submittal. Informational notices to submitters must be approved by the ONBS prior to publication.

## **SCOPE OF WORK**

### **SOLICITATION NO.: HP861156**

N. Educational Programs - The Contractor shall participate with the ONBS in the provision of newborn screening educational programs for physicians, nurses, and hospitals upon ONBS request but not more often than six times yearly. Contractor travel expenses are the responsibility of the Contractor.

O. Reference Materials - The Contractor shall seek and use reference materials for use in educational programs from existing programs nationwide.

P. Consultation and Program Support Activities - The Contractor shall provide clinical laboratory expertise and consultation support services for the ONBS regarding clinical laboratory practices. These consultation services are intended to assist the ONBS in the overall development, implementation and evaluation of the program. Consultation and program support activities include clinical laboratory expertise and consultation services provided by the Contractor to further the objectives of the ADHS. These services include, at a minimum, providing information and technical assistance to the ONBS regarding laboratory trends, research, testing methods, clinical laboratory issues, and laboratory operational issues regarding the performance of newborn screening. The Contractor, at a minimum, shall:

1. Attend and participate in monthly ONBS meetings. Attendance may be by video or audio teleconference connection.
2. Attend and participate in other committees or task forces as identified as necessary by the ONBS.
3. Collaborate with the ONBS Chief and other contractors involved in the provision of newborn screening and follow-up services, such as medical consultation and computerized data management systems.
4. Collaborate with the ONBS in the preparation of annual Newborn Screening reports for national newborn screening organizations and other government-sponsored agencies or associations.
5. Collaborate with the ONBS and its other Contractors in the design of specialized management reports from the Neometrics system. Prepare information or management reports related to screen testing or results of newborn screens for the ADHS and ONBS upon request.

Q. Transition Plan - Contractor shall provide a detailed transition plan for the change of location and service delivery from the current Newborn Screening contractor, the ADHS State Laboratory, to the Offeror.

R. Provide a monthly report, in accordance with a format approved by ADHS, containing, at a minimum, the following:

1. Number of first screens received during the report period
2. Number of second screens received during the report period
3. Number of unsatisfactory specimens, detailed by reason and submitter, total monthly and year to date;
4. Number of repeat and dietary monitoring screens received during the report period
5. Narrative description of Contractor quality management issues and concerns including:
  - a. Activities and accomplishments for the month;
  - b. Progress attained in meeting quality management goals;
  - c. Description of the types of education and/or technical assistance provided;
  - d. Reason for the education/technical assistance activities;
  - e. To whom the assistance was provided (submitter and personnel type);
  - f. Description of disputed billing items with submitters and their status;
  - g. Description of problems or concerns with other related ADHS Contractors or the Contractor's subcontractors in the performance of activities related to this contract (e.g., couriers, database vendors).
6. Narrative description of upcoming activities, challenges, barriers and/or changes;
7. Number of infants tested by collection source, total monthly and year to date;
8. Number of repeat screens by disorder/type of test requested, total monthly and year to date;
9. Presumptive positive test results, broken down by disorder;

# SCOPE OF WORK

## SOLICITATION NO.: HP861156

10. Amount billed to each payer, sent electronically to ADHS Accounting and ONBS Chief, total monthly and year to date;
11. Outstanding collection balances, detailed by payer;
12. Monthly elapsed time summary report, including:
  - a. Time from date and time of birth to date and time of specimen collection (<24 hours; 24-48 hours; 48-72 hours; ... >7 days);
  - b. Time from date and time of birth to date and time of receipt of first specimen (<24 hours; 24-48 hours; 48-72 hours; ... >7 days);
  - c. Time from date and time of birth to date and time of receipt of acceptable specimen (<24 hours; 24-48 hours; 48-72 hours; ... >7 days);
  - d. Time from date and time of specimen collection to date and time of receipt of specimen by the Contractor (<24 hours; 24-48 hours; 48-72 hours; ... >7 days);
  - e. Time from date and time of birth to date and time of reporting of test result (<24 hours; 24-48 hours; 48-72 hours; ... >7 days);
  - f. Time from date and time of receipt of specimen by the Contractor to date and time of reporting of test result (<24 hours; 24-48 hours; 48-72 hours; ... >7 days).

S. Prepare and submit an annual report summarizing activities, utilization, and effectiveness - The report is to be submitted within 45 days after the end of the contract year. The annual report shall, at a minimum, contain an evaluation of the effectiveness of the Contractor's clinical laboratory services and technical and program support activities, description of summary information regarding the number and types of tests performed, and continuous quality improvement activities and outcomes. In addition, it shall contain an annual quality assurance and improvement plan.

1. The Contractor's annual reports shall include:
  - a. Description of the activities involved in each of the subtasks specified in the contract, including quality assurance activities and technical assistance and education provided (quantitative summaries shall be included as appendices);
  - b. Evaluation efforts connected with each of the subtasks, unless described in another section of the report, including results of quality assurance activities;
  - c. Obstacles encountered and how they were addressed;
  - d. Personnel changes within Contractor Newborn Screening services
  - e. Results of any analysis of newborn screening data.
2. A summary of the number of tests of each type (first or second) performed, the number within each disease group that were negative and the number that were positive, the number of unsatisfactory specimens received, and the percentage of unsatisfactory first specimens and second specimens shall be included as an appendix.

T. DELIVERABLES - Contractor shall submit to the ONBS Chief:

<b>MONTHLY</b>
Invoice within 15 days of the end of each month;
Summary Report with each invoice
<b>ANNUAL</b>
Quality Assurance Plan within 45 days of the end of the contract year
Annual Summary Report within 45 days of the end of the contract year;
Business Continuity and Disaster Recovery Plan at initiation of contract year
<b>PRIOR TO SERVICE DELIVERY</b>
Copies of required licenses and/or certifications of key personnel prior to receipt of specimens for testing

<p style="text-align: center;"><b>SCOPE OF WORK</b> <b>SOLICITATION NO.: HP861156</b></p>
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Quality assurance plan prior to receipt of specimens for testing
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<b>OTHER REPORTS</b>
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As required by ADHS
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U. APPROVALS

1. Any changes to the specimen collection kits must be approved by the ONBS Chief prior to implementation.
2. Laboratory testing methodologies, cutoff values, results reporting methods, billing methods or substantive changes to any of the above, must be approved in writing by the ONBS Chief prior to implementation.
3. Monthly reports must be approved in writing by the ONBS Chief prior to authorization of payment of invoice.
4. Annual reports must be approved in writing by the ONBS Chief.
5. The Quality Assurance Plan must be approved in writing by the ONBS Chief prior to the contractor receiving specimens for testing.

V. Notices, Correspondence, Reports and Invoices "Contractors Expenditure Reports" from the Contractor to ADHS shall be mailed to:

Chief  
Office of Newborn Screening  
Bureau of Women's and Children's Health  
150 N 18<sup>th</sup> Ave., Suite 320  
Phoenix, Arizona 85007



# PRICE SHEET

## SOLICITATION NO.: HP861156

### I. AUTHORIZATION FOR PROVISION OF SERVICES

Authorization for purchase of services under this contract shall be made only upon ADHS issuance of a Purchase Order that is signed by an authorized agent. The Purchase Order will indicate the contract number and the dollar amount of funds authorized. The Contractor shall only be authorized to perform services up to the dollar amount on the Purchase Order. ADHS shall not have any legal obligation to pay for services in excess of the amount indicated on the Purchase Order. No further obligation for payment shall exist on behalf of ADHS unless: a) the Purchase Order is changed or modified with an official ADHS Procurement Change Order, and/or b) an additional Purchase Order is issued for purchase of services under this contract.

### II. PAYMENTS

1. Upon receipt of a valid invoice and any required reports, ADHS shall pay the Contractor monthly in accordance with the Contract Uniform Terms and Conditions, paragraph 4, Costs and Payments, for the contract payment rates as identified in this Contract.

2. The Contractor's invoice shall contain, at a minimum, the following:

- a. Number of first screens performed during the report period multiplied by the contracted reimbursement rate for a total charge;
- b. Number of second screens performed during the report period multiplied by the contracted reimbursement rate for a total charge;
- c. Number of unsatisfactory screens performed during the report period multiplied by the contracted reimbursement rate for a total charge;
- d. Number of screens performed during the report period multiplied by the contracted reimbursement rate for a total charge;
- e. The monthly charges for Education services;
- f. Total dollar amount invoiced;
- g. The Contract and Purchase Order number; and
- h. A remit to address.

### III. PAYMENT RATES

A.

Unit of Service	Unit of Measure	Rate Without the Cost of Bonds <sup>1</sup>	Rate With the Cost of Bonds <sup>2</sup>
First Screen	Per screen	\$	\$
Second Screen	Per screen	\$	\$
Unsatisfactory Screen	Per screen	\$	\$
Repeat and Dietary Monitoring Screen	Per screen	\$	\$
Education Services	Month of Service	\$	\$

1 – Rate Without the Cost of Bonds – Rate does not include the cost of the Contractor acquiring a Bid Bond or a Performance Bond as required by the contract Special Terms and Conditions.

2 – Rate With the Cost of Bonds – Rate includes the cost of the Contractor acquiring a Bid Bond and a Performance Bond as required by the contract Special Terms and Conditions.

<p style="text-align: center;"><b>PRICE SHEET</b> <b>SOLICITATION NO.: HP861156</b></p>
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- B. If the Contractor is required to provide a Bid Bond and a Performance Bond as required by the contract Special Terms and Conditions then the Contractor shall be paid the Rate With the Cost of Bonds.
- C. If the Contractor is not required to provide a Bid Bond and a Performance Bond as required by the contract Special Terms and Conditions then the Contractor shall be paid the Rate Without the Cost of Bonds.
- D. Unit of Service Defined:
- First Screen – Tasks A thru I, Q, R and S in the Scope of Work
  - Second Screen - Tasks A thru I, Q, R and S in the Scope of Work
  - Unsatisfactory Screen - Tasks A thru I, Q, R and S in the Scope of Work
  - Repeat and Dietary Monitoring Screen - Tasks A thru I, Q, R and S in the Scope of Work
  - Education Services – Tasks J thru P in the Scope of Work



# OFFER AND ACCEPTANCE

**Solicitation NO.: HP861156**

**Error! Main Document Only.**  
**Error! Main Document**  
**Only. ARIZONA**  
**DEPARTMENT OF**  
**HEALTH SERVICES**  
1740 W. Adams, Room 303  
Phoenix, Arizona 85007  
(602) 542-1040  
(602) 542-1741 Fax

Submit this form with an original signature to the:

**Arizona Department of Health Services**  
**Office of Procurement**  
**1740 West Adams, Room 303**  
**Phoenix, Arizona 85007**

The Undersigned hereby offers and agrees to furnish the material, service or construction in compliance with all terms, conditions, specifications and amendments in the solicitation.

Arizona Transaction (Sales) Privilege Tax License No:

For Clarification of this Offer, Contact:

Federal Employer Identification No:

Telephone:

FAX:

Company Name

Signature of Person Authorized to Sign Offer

Address

Printed Name

City, State, ZIP Code

Title

## OFFER ACCEPTANCE AND CONTRACT AWARD (For State of Arizona Use Only)

Your Offer is hereby accepted as described in the Notice of Award. The Contractor is now bound to perform based upon the Solicitation and the Contractor's Offer as accepted by the State.

This Contract shall henceforth be referred to as Contract Number:

**HP861156**

**The Contractor is hereby cautioned not to commence any billable work or provide any material, service or construction under this contract until the Contractor receives an executed purchase order or contract release document or written notice to proceed, if applicable.**

State of Arizona

Awarded this \_\_\_\_\_ day of \_\_\_\_\_, 2008

\_\_\_\_\_  
PROCUREMENT OFFICER

## OFFEROR'S QUALIFICATIONS QUESTIONNAIRE

### SOLICITATION NO. HP861156

Instructions: Complete each item, using attachments where necessary. Attachments shall indicate the item number and heading being referenced as it appears below. Failure to make full and complete disclosure may result in the rejection of your proposal as unresponsive.

1. Organization's Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Phone Number: \_\_\_\_\_ FAX: \_\_\_\_\_ Email Address: \_\_\_\_\_  
 Notices, Correspondence and Reports from ADHS to the Contractor shall be sent to this address unless otherwise indicated.

2. The Offeror is (check appropriate box):

<input type="checkbox"/>	Individual	<input type="checkbox"/>	Corporation - For Profit	<input type="checkbox"/>	Limited Liability Corporation/Company
<input type="checkbox"/>	Partnership	<input type="checkbox"/>	Corporation - Not For Profit	<input type="checkbox"/>	Government Entity

3. Authorized Signatories.

- A. \_\_\_\_\_  
 (Name and Title of Authorized Signatory) is the signatory to this Contract on behalf of the Contractor and is responsible for the delivery of Contract Services during the term of this Contract.
- B. In the absence of the principal authorized signatory named above,  
 \_\_\_\_\_  
 (Name, Title) is authorized to sign this Contract and any amendments thereto on behalf of the Contractor.
- C. \_\_\_\_\_  
 (Name, Title) is the Contractor's authorized representative, responsible for overall management of Contract services. ADHS shall address all notices relative to this Contract to the attention of same.

	YES	NO
4. Has any Federal or State agency ever made a finding of noncompliance with any relevant civil rights requirements with respect to your business activities? If YES, please attach an explanation.		
5. Has the Offeror, its major stockholders with a controlling interest, or its officers been the subject of criminal investigations or prosecutions or convicted of a felony? If YES, please attach an explanation.		
6. Does the Offeror have sufficient funds to meet obligations on time under the Contract while awaiting reimbursement from ADHS? If NO, please attach an explanation.		
7. Have any licenses ever been denied, revoked or suspended or provisionally issued within the past five years? If YES, please attach an explanation.		
8. Have you or has your organization terminated any contracts, had any contracts terminated, had any liquidated damages assessed or been involved in contract lawsuits? If YES, please attach an explanation.		
9. Do you, your staff, any of your relatives, or voting members of your Board of Directors maintain any ownerships, employments, public and private affiliations or relationships which may have substantial interest (as defined in A.R.S. §38-502, Conflict of Interest) in any contract, sale, purchase, or service involving ADHS? If YES, please attach an explanation.		
10. Has your organization ever gone through bankruptcy? If YES, When? Include the State, District and case number.		

# OFFEROR'S QUALIFICATIONS QUESTIONNAIRE

## SOLICITATION NO. HP861156

For the following questions label your response "Offeror's Qualifications Questionnaire" and indicate the question number.

12. Provide an overview of the company's history and structure including an organization chart.
12. Describe the company's experience and expertise in providing laboratory testing services including experience in testing methodologies used for newborn screening. Indicate the Offeror's ability to perform services as reflected by availability and suitability of staff, equipment, and facility resources. The response is limited to ten (10) pages, single-sided with one-inch margins and number 12 font.
13. Describe the company's ability and capability to perform laboratory testing using Tandem Mass Spectrometry, Immunoassay, High Performance Liquid Chromatography, and deoxyribonucleic acid (DNA) analysis instruments.
14. Provide an organizational chart of the proposed staff providing and overseeing newborn screening laboratory procedures, including use of subcontractors. Indicate if positions will be filled with current staff or if a new position(s) would be created as a result of contract award and percentage of time that position will be dedicated to providing and/or overseeing newborn screening laboratory procedures under this contract.

From the organizational chart provide the name, position currently held in the company, the primary function(s) of this person in terms of providing services under the resulting Contract, credentials and experience for each person responsible for providing and/or overseeing newborn screening laboratory procedures under this contract. This shall include the Project Manager (as identified in the Scope of Work), those individuals who will be providing direct supervision of newborn screening laboratory activities or determining procedural steps in the analysis of newborn screening. At a minimum this shall include resumes or Curriculum Vitae, employment history, educational preparation, professional licensure, certifications, professional awards, publications, and educational offerings. Indicate percentage of time each will be assigned to the ADHS account.

15. Provide a list of at least three (3) current clients or clients served within the past three (3) years for whom your company has provided similar services that can describe and evaluate the performance of the Offeror's work on the project(s). Identify which are active accounts. Include a brief description of services provided. These clients will serve as references. Be sure to include business name, and the name, title, phone number and email address of a contact person. These clients will be contacted to assess the Offeror's past service delivery record.
16. Provide the following:
  - A. Documentation that verifies the Offeror's laboratory personnel are licensed and certified according to Clinical Laboratory Improvement Act (CLIA) 88 regulations for High Complexity Laboratory Testing (Federal Register, Vol. 57, No. 49, 2/28/92).
  - B. Documentation that verifies the Offeror's laboratory facility is licensed by the appropriate state licensing authority and is certified by CLIA. Provide the most recent CLIA certification findings and any proposed or imposed sanctions and your responses to these sanctions.
  - C. Documentation that verifies the Laboratory Director meets licensing and CLIA qualifications (CLIA 88 regulations for High Complexity Testing.)

**EXHIBIT**  
**BID BOND**

**KNOW ALL MEN BY THESE PRESENTS:**

THAT, \_\_\_\_\_, (hereinafter called Principal), as Principal and  
, a corporation organized and existing under the laws of the State of \_\_\_\_\_, with its principal  
office in the City of \_\_\_\_\_, (hereinafter called the Surety), as Surety, are held and firmly bound  
unto the State of Arizona, (hereinafter called the Oblige), in the amount  
of \_\_\_\_\_ (Dollars) (\$\_\_\_\_\_.00), for the payment whereof, the said Principal  
and Surety bind themselves, and their heirs, administrators, executors, successors and assigns, jointly and severally,  
firmly by these presents.

WHEREAS, the Principal has submitted a bid for:

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION IS SUCH, that if the said Principal shall faithfully  
perform and fulfill all the undertakings, covenants, terms, conditions, and agreements of said contract during the  
original term of said contract and any extension thereof, with or without notice to the Surety and during the life of any  
guaranty required under the contract, and shall also perform and fulfill all the undertakings, covenants, terms,  
conditions, and agreements of any and all duly authorized modifications of said contract that may hereafter be made,  
notice of which modifications to the Surety being hereby waived: then the above obligations shall be void, otherwise  
to remain in full force and effect.

The prevailing party in a suit on this bond shall recover, as part of his judgment, such reasonable attorney's fees as  
may be fixed by a judge of the Court.

Witness our hands this \_\_\_\_\_ day of \_\_\_\_\_ 2008.

	Principal	Seal
BY		
	Surety	Seal
BY		
	Agency of Record	

**EXHIBIT**  
**PERFORMANCE BOND**

Supplier Name: \_\_\_\_\_

KNOW ALL PERSONS BY THESE PRESENTS:

THAT, \_\_\_\_\_ (hereinafter called Principal), as Principal, and \_\_\_\_\_, a corporation organized and existing under the laws of the State of \_\_\_\_\_ with its principal office in the city of \_\_\_\_\_ (hereinafter called the Surety), as Surety, are held and firmly bound unto the State of Arizona, (hereinafter called Oblige) in the amount of \_\_\_\_\_ (Dollars) (\$ \_\_\_\_\_), for the payment whereof, the said Principal and Surety bind themselves and their heirs, administrators, executors, successor assigns, jointly and severally firmly by these presents.

WHEREAS, the Principal has entered into a certain written contract with the oblige, dated the \_\_\_\_\_ day of \_\_\_\_\_, for the material, service or construction described as: **Newborn Screening Laboratory Services** In accordance to the Arizona Procurement Code, ARS 41-2501 et seq., The Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health, Office of Newborn Screening (ONBS) is soliciting proposals in order to establish a contract for newborn screening clinical laboratory services, technical laboratory assistance and educational services to specimen submitters and program support. In accordance with A.R.S. §36-694, section I, proposals may be accepted from hospitals, clinical laboratories licensed pursuant to A.R.S. §36-461 to 36-479, the state laboratory (the ADHS State Laboratory) described in A.R.S. §36-251, and any other qualified public or private persons.

For questions relating to the solicitation or procurement process, please contact Jamie Alton at (602) 542-1043 or via email at [Altonj@azdhs.gov](mailto:Altonj@azdhs.gov)

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A pre-offer conference has been scheduled on February xx, 2008, at 10:00 AM (Arizona time.) This is not mandatory, however, all offerors and interested parties are encouraged to attend this meeting. The purpose of this conference will be to clarify the contents of this request for proposals in order to prevent any misunderstanding of the Department's position. Any doubt as to the requirements of this request for proposals or any apparent omission or discrepancy should be presented to the Department at this conference or in accordance with the terms and conditions provided herein. The Department will then determine the appropriate action necessary, if any, and may issue a written amendment to the request for proposals. Oral statements or instructions shall not constitute an amendment to this request for proposals

which contract is hereby referred to and made a part hereof as fully and to the same extent as if copied at length herein.

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION IS SUCH, that if the said Principal shall faithfully perform and fulfill all the undertakings, covenants, terms, conditions and agreements of said contract during the original term of said contract and any extension thereof, with or without notice to the Surety and during the life of any guaranty required under the contract, and shall also perform and fulfill all the undertakings, covenants, terms, conditions, and agreements of any and all duly authorized modifications of said contract that may hereafter be made, notice of which modifications to the Surety being hereby waived; then the above obligations shall be void, otherwise to remain in full force and effect.

The prevailing party in a suit on this bond shall recover as part of his judgment such reasonable attorneys' fees as may be fixed by a judge of the Court.

Witness our hands this \_\_\_\_\_ day of \_\_\_\_\_.

\_\_\_\_\_  
Principal Seal

\_\_\_\_\_  
By

\_\_\_\_\_  
Surety Seal

\_\_\_\_\_  
By

\_\_\_\_\_  
Agency of Record